

# EXHIBIT C.1

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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MARY K. JONES, Individually and on Behalf  
of All Others Similarly Situated,

Plaintiff

vs.

PFIZER INC., HENRY A. McKINNELL,  
JEFFREY B. KINDLER, FRANK  
D'AMELIO, DAVID L. SHEDLARZ, ALAN  
G. LEVIN, IAN C. READ, JOSEPH FECZKO,  
KAREN KATEN, J. PATRICK KELLY and  
ALLEN WAXMAN,

Defendants.

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x

Civil Action No. 1:10-cv-03864-AKH

CLASS ACTION

FIRST AMENDED CONSOLIDATED  
CLASS ACTION COMPLAINT FOR  
VIOLATIONS OF THE FEDERAL  
SECURITIES LAWS

x

DEMAND FOR JURY TRIAL

Text highlighted  
in yellow  
indicates  
portions of the  
complaint  
withdrawn by  
Plaintiffs.

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## SUMMARY OF THE ACTION

1. This securities fraud class action is brought pursuant to §§10(b) and 20(a) of the Securities Exchange Act of 1934 (“1934 Act”) on behalf of all persons who purchased Pfizer Inc. (“Pfizer” or the “Company”) securities between 1/19/06 and 1/23/09 (the “Class Period”) against Pfizer and certain of its senior executives arising out of defendants’ false statements to investors concerning Pfizer’s unlawful off-label marketing of Pfizer’s pharmaceutical products, including Bextra, Geodon, Lyrica and Zyvox, and the illegal payment of kickbacks to physicians to promote the sale of these drugs.<sup>1</sup> Defendants’ false and misleading statements about Pfizer’s financial performance and sales practices caused Pfizer stock to trade at artificially inflated prices throughout the Class Period. On 1/26/09, the price of Pfizer stock dropped when defendants were forced to reveal Pfizer’s illegal marketing and sales practices and the fees that the Company had agreed to pay a record \$2.3 billion in criminal and civil fines and penalties as a result thereof.

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## INTRODUCTION

2. This is not the first time that Pfizer has faced criminal sanction for the unlawful marketing of its drugs. In 2004, Pfizer paid \$430 million to settle criminal charges for its illegal off-

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<sup>1</sup> The individual defendants include: Jeffrey B. Kindler (“Kindler”) (Chief Executive Officer (“CEO”) of the Company from 2006 to 12/5/10 and Chairman of the Board from 2/07 to 12/5/10); Henry A. McKinnell (“McKinnell”) (CEO from 2001 to 2006 and Chairman of the Board from 2001 until his retirement in 2/07); Frank D’Amelio (“D’Amelio”) (Chief Financial Officer (“CFO”) since 9/07); David L. Shedlarz (“Shedlarz”) (Executive Vice President and CFO from 1/99 to 7/05, and Vice Chairman from 3/05 until his retirement in 12/07); Alan G. Levin (“Levin”) (Senior Vice President and CFO of the Company from 3/05 until his retirement in 9/07); Ian C. Read (“Read”) (Senior Vice President and Group President, Worldwide Biopharmaceutical Operations of the Company from 2006 to 12/5/10 and current CEO); Joseph Feczko (“Feczko”) (Chief Medical Officer until his retirement in 12/08); Karen Katen (“Katen”) (Vice Chairman of Pfizer and President of Pfizer Human Health until her retirement in 3/07); Allen Waxman (“Waxman”) (General Counsel until his retirement in 3/08); and J. Patrick Kelly (“Kelly”) (Vice President of Pfizer and President of U.S. Pharmaceuticals).

label promotion of Neurontin. As it was finalizing that settlement, and throughout the Class Period, Pfizer continued to illegally market drugs off-label. Ultimately, this misconduct resulted in the Company being forced to pay the largest criminal fine in the history of the United States.

3. During the Class Period, Pfizer's business strategy was built around a growth strategy that aggressively marketed drugs to doctors for purposes for which the drugs were not approved by the U.S. Food and Drug Administration ("FDA") or scientifically proven to benefit patients. Under the U.S. Food, Drug and Cosmetic Act ("FDCA"), pharmaceutical companies must seek approval from the FDA to market a drug to physicians by providing clinical data proving that the drug is safe and effective for particular indications. The purpose of the FDCA and relevant FDA regulations is to protect patients from medications that have not been demonstrated to be effective and safe.

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4. The FDA expressly forbids drug companies from promoting unapproved drugs, approved drugs for unapproved indications and approved drugs for unapproved doses or unapproved patient populations. For example, a drug manufacturer cannot promote a drug approved for adults to children or adolescents. The practice of promoting drugs for unapproved uses is referred to as "off-label" marketing. Since 2004, the practice of illegally promoting drugs off-label has received major headlines and considerable scrutiny from state and federal prosecutors.

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5. As a result of illegal off-label promotion, Warner-Lambert, acquired by Pfizer, drastically increased Neurontin sales via off-label marketing by more than 2,700% between 1995 and 2008, from \$97.5 million to almost \$2.7 billion.<sup>2</sup> As part of the 2004 Neurontin settlement, Pfizer not only paid over \$430 million to settle criminal and civil violations relating to its unlawful

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<sup>2</sup> According to the prosecutor who led the investigation, Michael Loucks ("Loucks"), 94% of Neurontin's sales were off-label. Loucks attributed the sales to Pfizer making "a concerted effort to push for off-label uses."

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promotion of Neurontin, it executed a Corporate Integrity Agreement (“CIA”) with the Office of Inspector General of the United States Department of Health and Human Services (“OIG”), in which Pfizer promised to detect and prevent off-label marketing. Ex. A (attached hereto).

6. Notwithstanding the settlement and Pfizer’s representations to the federal court, prosecutors and Pfizer shareholders, the illegal off-label promotion of drugs continued unabated at Pfizer. In fact, even as Pfizer was finalizing the Neurontin settlement and executing the 2004 CIA, defendants continued illegally marketing Pfizer’s drugs off-label. According to an article appearing in *Bloomberg* on 11/9/09: D\*\*

Prosecutor Michael Loucks [the U.S. Attorney for the District of Massachusetts] remembers clearly when lawyers for Pfizer Inc., the world’s largest drug company, looked across the table and promised it wouldn’t break the law [against off-label marketing] again.

\* \* \*

What Loucks, who’s now acting U.S. attorney in Boston, didn’t know until years later was that ***Pfizer managers were breaking that pledge not to practice so-called off-label marketing even before the ink was dry on their plea.***

\* \* \*

“They asserted that the company understood the rules and had taken steps to assure corporate compliance with the law,” Loucks says. “We remember those promises.”

What Pfizer’s lawyers didn’t tell prosecutors was that ***Pfizer was at that moment running an off-label marketing promotion using more than 100 of its salespeople.*** They were pitching Bextra, a Pfizer sales manager admitted when she pleaded guilty to misbranding a drug on March 30, 2009.

7. Despite Pfizer’s assurances that the Neurontin off-label marketing practices occurred only at Warner-Lambert and prior to Warner-Lambert’s acquisition by Pfizer, Pfizer was – both prior to and during the Class Period – actively promoting Bextra, Geodon and Zyvox for off-label indications by employing similar illegal marketing tactics to those used to unlawfully promote Neurontin. And Pfizer was doing so with clear knowledge of the material adverse risks to the D\*

617336\_2 D\* = Defendants admitted certain facts in connection with this paragraph in their Amended Answer, and those admissions are incorporated by reference here.

D\*\* = As indicated in their Amended Answer, Defendants respectfully refer the Court to the cited document[s] for its/their complete content.

Company. A PowerPoint presentation entitled “The ‘Bottom Line’ Analysis: the In-House View” prepared by Pfizer’s assistant General Counsel for the Health Care Compliance Association (HCCA) 2005 Annual Compliance Institute confirms Pfizer’s knowledge by the beginning of the Class Period that non-compliance with relevant laws (such as the prohibition on off-label marketing) bears costs including fines, civil judgments, exclusion, reputation and stock price. The presentation also acknowledges that prosecutions (and penalties) had increased for non-compliance.

8. Pfizer promoted Bextra for the relief of acute pain even though clinical data did not support that indication and the FDA had rejected the application for that indication. In 4/05, the FDA forced Pfizer to remove Bextra from the market because it caused an increased risk of heart attacks and a severe skin reaction, risks that Pfizer downplayed in its marketing.

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9. Pfizer was also promoting off-label uses of Geodon at the same time it was settling the Neurontin investigation in 2004. Pfizer received FDA approval to market Geodon for schizophrenia, manic bipolar episodes and schizophrenia-related intramuscular pain. However, during the Class Period, defendants secretly marketed the drug for multiple off-label indications including depression, mood disorder, anxiety, aggression, dementia and attention deficit hyperactivity disorder, as well as for patients (pediatric and adolescent patients) and dosages that were unapproved. The unlawful off-label marketing of Geodon continued through the end of 2007.

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10. Pfizer also illegally promoted Zyvox during the Class Period for a variety of off-label conditions, including for infections caused by Methicillin-resistant staphylococcus aureus (“MRSA”) related to cancer and dialysis treatments, when the drug was not approved for these indications. Further, defendants also illegally promoted Zyvox during the Class Period by saying that it was *more* effective than vancomycin, even though the Company received a letter from the

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FDA prior to the Class Period in 2005 (the “2005 FDA Warning Letter”) specifically warning Pfizer not to make that claim.

11. Beginning in 9/05 Pfizer started using the same illegal methods to promote Lyrica (a drug designed to replace Neurontin) that Pfizer had previously pled guilty to using with respect to Neurontin. Continuing at least through the end of 10/08, Pfizer illegally promoted Lyrica for a wide variety of off-label uses including chronic pain, neuropathic pain, preoperative pain, migraines, mood improvement and anxiety, even though it had only obtained FDA approval for Lyrica to treat diabetic peripheral neuropathy (“DPN”), postherpetic neuralgia (“PHN”) and, later, fibromyalgia.

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12. Although defendants continued and even increased Pfizer’s off-label marketing efforts following the Neurontin settlement, defendants falsely assured investors in Pfizer’s Securities and Exchange Commission (“SEC”) filings and other public statements that the Company had controls that prevented the unlawful promotion of its drugs. In Pfizer’s SEC filings defendants expanded on Pfizer’s Policies on Business Conduct (“Policies” or the “Blue Book”), misleading investors into believing that Pfizer’s existing controls prevented such unlawful practices and that its prior unlawful, off-label marketing practices had ceased. ¶¶58-67, 77.

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13. Defendants were well aware of the materially adverse risks to Pfizer from its illegal off-label marketing, including massive criminal and civil fines and debarment from any federal healthcare program. Yet, defendants deliberately concealed this information from investors. For example, defendants Kindler, McKinnell, Feczko and Read have admitted in court filings that by 2/04, Pfizer knew of the government’s Bextra off-label marketing investigation. Likewise, Pfizer senior management was aware of the off-label marketing of Lyrica and Geodon no later than the fall of 2006. Defendants also knew of the off-label marketing of Zyvox no later than 7/05, when Pfizer received the 2005 FDA Warning Letter, and knew of the government’s investigation of the illegal

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promotion of Zyvox no later than 12/07. Pfizer's current General Counsel confirms in a 9/14/09 *National Law Journal* article that settlement negotiations with the U.S. Department of Justice ("DOJ") began prior to 6/08, when she joined the Company.

14. Further, senior management was tasked with advising Pfizer's Audit Committee promptly of compliance matters, and employed a tracking chart to monitor the *qui tams* and other complaints. This knowledge stands in stark contrast to defendants' public representations and the reserves Pfizer was required to take during the Class Period, but did not, for its unlawful conduct.

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15. Defendants caused Pfizer to file with the SEC false and misleading Forms 10-Q and Forms 10-K. ¶¶68-77. Throughout the Class Period, defendants concealed that Pfizer was engaging in illegal off-label promotions and failed to inform investors of the materially adverse risks the Company faced as a result. And when the Company did finally begin to reveal that it had received "requests for information" regarding the "marketing of Celebrex and Bextra," it continued to conceal that Pfizer: (i) had illegally promoted Bextra and was continuing to unlawfully market Geodon, Zyvox and Lyrica off-label; (ii) that Pfizer's pattern and practice of illegal off-label promotions exposed it to a real risk of being banned from federal as well as state funded healthcare programs (*e.g.* Medicaid); (iii) was violating its own corporate Policies against off-label marketing; (iv) did not possess adequate internal controls to prevent, detect and stop off-label marketing; (v) was facing massive criminal and civil investigations; and (vi) faced materially adverse financial consequences that required contingency reserves.

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16. Pfizer's later disclosures that it was working to resolve investigations were also false and misleading because the Company actively concealed that it had been illegally promoting products. The term "off-label" appears nowhere in these sections of Pfizer's SEC filings even though defendants were aware that this illegal practice would force the Company to pay record-level

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criminal fines and civil penalties. Even worse, Pfizer's SEC filings deliberately downplayed the material risks of Pfizer's unabated off-label marketing after promises not to engage in such practices, claiming that any "government investigations" would not have "a material adverse effect material risks on [Pfizer's] financial condition." Yet, defendants knew that Pfizer's corporate reputation, its financial condition and its very existence were at risk as a result of federal law mandating debarment from government-funded health programs.

17. Pfizer's publicly issued financial statements during the Class Period were also materially misstated in violation of U.S. Generally Accepted Accounting Principles ("GAAP") and SEC rules because Pfizer: (i) failed to timely record a minimum of a \$2.3 billion loss reserve for its illegal off-label promotional practices; (ii) failed to disclose that the Company had submitted hundreds of millions of dollars in false or fraudulent claims, based on illegal off-label marketing, to federal and state healthcare programs, thus exposing the Company to multi-billion dollar legal liability; (iii) misrepresented the nature and the severity of the DOJ and state attorneys general investigations; and (iv) misrepresented the true nature of the Company's significant revenue growth reported from the sales of Geodon, Lyrica and Zyvox and its ability to meet its earnings targets. Pfizer's reported income and earnings were materially overstated and its disclosures omitted material information necessary for its financial results to be fairly and accurately presented to investors. *See* ¶¶78-80.

18. Throughout the Class Period, defendants' statements about how Pfizer had achieved increased Geodon, Zyvox and Lyrica drug sales were false and misleading because they omitted the fact that Pfizer was only able to achieve its reported growth by utilizing illicit off-label promotions. ¶¶84-94. Pfizer also misrepresented the results of clinical studies to increase off-label sales to physicians and thereafter misrepresented those same clinical studies to investors. ¶¶88-89.

19. On 1/26/09, Pfizer stunned investors by announcing that the Company had agreed to pay \$2.3 billion to resolve criminal and civil investigations stemming from its continued unlawful off-label marketing of Bextra and three other drugs. The \$1.3 billion criminal fine represents the largest criminal fine in U.S. history. To distract the market, defendants and their counsel made a decision to contemporaneously announce Pfizer's acquisition of Wyeth on the very same day. Despite Pfizer's efforts to downplay that it was subject to the largest criminal fine in U.S. history, news of Pfizer's acquisition of Wyeth actually leaked into the market before the markets opened on 1/23/09. As news of that merger was absorbed on 1/23/09, Pfizer's stock price actually increased 1.3%. On 1/26/09 the market reacted to the stunningly adverse revelation that Pfizer faced \$2.3 billion in penalties for off-label marketing. The price of Pfizer common stock declined from \$17.45 to \$15.65 on 1/26/09 as the artificial inflation caused by defendants' misrepresentations and omissions came out of the stock price, resulting in massive losses to Pfizer's investors and a single day loss in Pfizer's market capitalization of more than \$12 billion.

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### JURISDICTION AND VENUE

20. The claims asserted arise under §§10(b) and 20(a) of the 1934 Act and Rule 10b-5. Jurisdiction is conferred by §27 of the 1934 Act. Venue is proper pursuant to §27 of the 1934 Act. Pfizer's headquarters are located in New York, New York, and false statements were made in this District and acts giving rise to the violations complained of occurred in this District.

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### THE PARTIES

21. Lead Plaintiff Stichting Philips Pensioenfond purchased Pfizer securities during the Class Period on the New York Stock Exchange ("NYSE") as set forth in the attached certification and was damaged thereby.

Defendants admit allegations highlighted in blue but otherwise deny the allegations in this paragraph.

22. Plaintiff Mary K. Jones purchased Pfizer securities during the Class Period on the NYSE as set forth in the attached certification and was damaged thereby.

Defendants admit allegations highlighted in blue but otherwise deny the allegations in this paragraph.

23. Defendant Pfizer is a pharmaceutical company with its headquarters located in New York, New York. Pfizer is considered the world's largest research-based biopharmaceutical company. Pfizer's stock is traded under the symbol PFE on the NYSE, which is an efficient market.

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24. Defendant Jeffrey B. Kindler has served in various executive positions with Pfizer since 2002. From 1/02 to 7/06, Kindler was Pfizer's General Counsel. He was the CEO and Chairman of the Board, from 7/06 and 2/07 to 12/5/10, respectively. As CEO and Chairman, Kindler was ultimately responsible for all aspects of Pfizer's business, including discovering, developing, manufacturing and marketing Pfizer's prescription medicines. Kindler was also Chair of Pfizer's Board Executive Committee and a member of the Executive Leadership Team and Executive Compliance Committee. As one of the four members of the Executive Committee, Kindler was a part of Pfizer's most senior decision-making team responsible for compliance, legal, communications, government relations, corporate citizenship, policy development, vision, strategic direction and operation of Pfizer. The committee reviews and approves all major management, operating and financial decisions. It also has accountability and direct control over nearly all of Pfizer's operating and support groups.

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25. In 2005, Kindler was both the General Counsel and the Chief Compliance Officer as required under the terms of the 2004 CIA. In these roles, Kindler was responsible for developing and implementing the Code of Conduct and procedures to ensure compliance with federal healthcare laws, and for monitoring the day-to-day compliance activities. In his role as Chief Compliance Officer, he was responsible for overseeing the Corporate Compliance Committee, which reviewed off-label marketing issues reported via the Company's hotline reporting system put in place for

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employees to report illegal marketing. As Chief Compliance Officer, he was also responsible for reporting off-label marketing matters at least semi-annually to the Board of Directors and the Audit Committee of the Board.

26. Kindler signed or authorized to be signed the 3/1/07 and 2/29/08 Forms 10-K, including the attached Sarbanes-Oxley Certifications. Kindler also signed or authorized to be signed the Sarbanes-Oxley Certifications attached to the 8/11/06, 11/3/06, 5/4/07, 8/6/07, 11/5/07, 5/2/08, 8/8/08 and 11/7/08 Forms 10-Q. Kindler participated in a number of conference calls during the Class Period, including, but not limited to, the 3Q06, 1Q07, 2Q07, 3Q07, 4Q07, 1Q08, 2Q08 and 3Q08 Pfizer earnings calls and the 2/10/06 and 1/22/07 Pfizer analyst meetings. Kindler unexpectedly announced his “retirement” on the evening of 12/5/10.

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27. Defendant Henry A. McKinnell served in various executive positions with Pfizer from 1971 to 2007. McKinnell was the Company’s CEO from 2001 to 7/06 and Chairman of the Board from 2001 until his retirement in 2/07. From 1984 until he became CEO in 2001, McKinnell served in a number of executive capacities, including Vice President of Strategic Planning, CFO, President of Pfizer Medical Service Group, President of Pfizer Pharmaceuticals Group and Chief Operating Officer (“COO”). McKinnell signed or authorized to be signed the 3/1/06 and 3/1/07 Forms 10-K, including the Sarbanes-Oxley Certification attached to the 2006 Form 10-K. McKinnell also signed the Sarbanes-Oxley Certification attached to the 5/8/06 Form 10-Q. McKinnell participated in conference calls during the Class Period, including, but not limited to, the 4Q05, 1Q06 and 2Q06 Pfizer earnings calls and the 2/10/06 analyst meeting.

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28. Defendant Frank D’Amelio has served as the Company’s CFO since 9/07. As CFO, D’Amelio is responsible for both the financial and business operations of Pfizer. D’Amelio is a member of Pfizer’s Executive Leadership Team and Executive Compliance Committee. D’Amelio

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signed the 2/29/08 Form 10-K, including the Sarbanes-Oxley Certification attached. D'Amelio also signed the Sarbanes-Oxley Certifications attached to the 11/5/07, 5/2/08, 8/8/08 and 11/7/08 Forms 10-Q. D'Amelio participated in a number of conference calls during the Class Period, including, but not limited to, the 3Q07, 4Q07, 1Q08, 2Q08 and 3Q08 Pfizer earnings calls and the 5/5/08 Deutsche Bank Securities Health Care Conference.

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29. **Defendant** David L. Shedlarz served various capacities at Pfizer from 1971 to 2007. Shedlarz was the Company's Executive Vice President and CFO from 1/99 to 7/05, and served as Vice Chairman from 3/05 until his retirement in 12/07. Shedlarz was also a member of Pfizer's Executive Committee. Shedlarz participated in a number of Pfizer conference calls during the Class Period, including, but not limited to, the 4Q05, 1Q06, 2Q06, 3Q06, 1Q07, 2Q07 and 3Q07 Pfizer earnings calls, the 2/10/06 and 1/22/07 analyst meetings and the 5/2/06 Deutsche Bank Securities 31st Annual Health Care Conference.

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30. Defendant Alan G. Levin was Pfizer's Senior Vice President and CFO of the Company from 3/05 to 9/07. Prior to being Pfizer's CFO, Levin served in various finance and accounting related capacities at Pfizer beginning in 1987. Levin signed Pfizer's 3/1/06 and 3/1/07 Forms 10-K, including the Sarbanes-Oxley Certifications attached. Levin also signed the Sarbanes-Oxley Certifications attached to the 5/8/06, 8/11/06, 11/3/06, 5/4/07 and 8/6/07 Forms 10-Q. Levin participated in a number of Pfizer conference calls during the Class Period, including, but not limited to, the 4Q05, 3Q06 and 2Q07 Pfizer earnings calls and the 1/22/07 analyst meeting.

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31. Defendant Ian C. Read has served in various executive positions with Pfizer since 1978, including as Pfizer's Senior Vice President and Group President of the Worldwide Biopharmaceutical Operations of the Company from 2006 to 12/5/10 and the Company's current CEO. As President of the Worldwide Biopharmaceutical Operations, Read was the head of the

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<sup>617336\_2</sup>D\* = Defendants admitted certain facts in connection with this paragraph in their Amended Answer, and those admissions are incorporated by reference here.



world's largest organization devoted to developing, marketing and selling of prescription drugs. Read is also a member of Pfizer's Executive Leadership Team, Executive Compliance Committee and, as of 12/5/10, its Board of Directors. Read participated in a number of Pfizer conference calls during the Class Period, including, but not limited to, the 4Q05, 1Q06, 3Q06, 1Q07, 2Q07, 3Q07, 4Q07, 1Q08, 2Q08 and 3Q08 Pfizer earnings calls, the 1/22/07 analyst call and the 9/22/08 UBS Global Life Sciences Conference.

32. **Defendant** J. Patrick Kelly served in various capacities at Pfizer between 1981 and 2006. Prior to being promoted to Vice President of Pfizer and President of U.S. Pharmaceuticals in 2002, a position he held until his departure in 8/06, Kelly held a number of marketing positions, including Group Vice President for Disease Management and Senior Vice President of Worldwide Marketing. During his marketing career at Pfizer, Kelly built and managed teams that developed and implemented educational and promotional programs in support of Pfizer medicines. Kelly was also a member of the Pfizer Pharmaceuticals Group Leadership Team and the Management Council. Kelly participated in the 4Q05 and 2Q06 Pfizer earnings calls, the 2/10/06 Pfizer analyst meeting and the 5/2/06 Deutsche Bank Annual Health Care Conference.

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33. **Defendant** Joseph Feczko served in various positions at Pfizer for 22 years. During the Class Period, Feczko was Pfizer's Chief Medical Officer and a member of the Executive Leadership Team until his retirement in 5/09. As Chief Medical Officer, Feczko was responsible for all aspects of Pfizer's medical affairs, including regulatory matters, medical policies and safety activities. Feczko participated in Pfizer conference calls during the Class Period, including, but not limited to, the 4Q05, 1Q06, 2Q06 and 3Q06 Pfizer earnings calls and the 2/10/06 and 1/22/07 analyst meetings.

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34. **Defendant** Karen Katen served in various capacities at Pfizer since 1974. From 3/05 to 3/07 Katen was Vice Chairman and President of Pfizer Human Health. Pfizer Human Health is the Company's principal operating group, that Katen was responsible for the discovery, development, manufacture, distribution and commercialization of Pfizer's prescription medicines. Katen participated in Pfizer conference calls during the Class Period, including, but not limited to, the 1Q06 and 2Q06 Pfizer earnings calls and the 2/10/06 analyst meeting. D\*

35. Defendant Allen Waxman began working in Pfizer's General Counsel's office in 2003. In 2006 Waxman was appointed General Counsel and served in that capacity until he departed in 2008. After the Board of Directors selected Kindler to become Pfizer's CEO in 2006, Waxman became the Company's General Counsel and therefore had the responsibility to ensure Pfizer's compliance with the FDCA, FDA regulations regarding illegal off-label marketing, the False Claims Act and federal healthcare programs. As General Counsel, Waxman was also responsible for setting strategy for Pfizer's most significant legal and regulatory matters, including regulatory inquiries, litigation, employment matters and intellectual property issues. Waxman was also a member of Pfizer's Executive Leadership Team, and participated in Board and Audit Committee meetings. Waxman participated in Pfizer conference calls during the Class Period, including, but not limited to, the 3Q06, 1Q07, 2Q07, 3Q07 and 4Q07 Pfizer earnings calls and the 1/22/07 Pfizer analyst meeting. D\*

36. The defendants named in ¶¶24-35 are referred to herein as the "Individual Defendants."

#### **DEFENDANTS' ILLEGAL MARKETING PRACTICES**

37. Pfizer was founded in 1849 and is in the business of developing, manufacturing and selling pharmaceuticals. As such, Pfizer's operations are regulated by the FDA. During the Class Period, defendants illegally promoted the sale of drugs such as Bextra, Geodon, Lyrica and Zyvox. D\*

for uses unapproved by the FDA and, in certain instances, uses that the FDA had specifically told Pfizer were not permitted. The illegal conduct was systemic and directly or indirectly sanctioned by defendants.

38. Prior to the Class Period, on 5/13/04, a Pfizer subsidiary, Warner-Lambert, agreed to plead guilty to a felony and pay more than \$430 million to resolve criminal charges and civil liabilities in connection with the illegal and fraudulent promotion of unapproved uses for Neurontin. According to the DOJ press release to announce the Neurontin settlement: “Warner-Lambert’s strategic marketing plans, as well as other evidence, show that *Neurontin was aggressively marketed to treat a wide array of ailments for which the drug was not approved.*” The DOJ also noted that “Warner-Lambert promoted Neurontin even when scientific studies had shown it was not effective.”

39. The DOJ release set forth the off-label marketing tactics Warner-Lambert employed to illegally promote the unapproved uses of Neurontin, including:

- encouraging sales representatives to meet one-on-one with physicians to pitch off-label uses without prior inquiry by doctors;
- sales representatives making false and misleading statements to health care professionals regarding the drug’s efficacy and whether it had been approved by the FDA for off-label uses;
- utilizing “Medical Liaisons” who falsely represented themselves as scientific experts to promote off-label uses;
- paying physicians to attend “consultants meetings” including expensive dinners or out-of-town conferences – such as trips to Florida, the 1996 Atlanta Olympics and Hawaii – during which presentations about off-label uses were made;
- sales representatives recruiting physicians to call a pre-arranged number to listen to other physicians or sales representatives speak about off-label uses;
- funding purportedly independent continuing medical education (“CME”) conferences on off-label uses where Warner-Lambert controlled the speakers, topics, content and participants;

617336\_2 D\* = Defendants admitted certain facts in connection with this paragraph in their Amended Answer, and those admissions are incorporated by reference here.

D\*\* = As indicated in their Amended Answer, Defendants respectfully refer the Court to the cited document[s] for its/their complete content.

- planting people in the audience of CME conferences to ask questions about the off-label uses of Neurontin; and
- paying physicians to allow sales representatives to accompany the physician while seeing patients.

40. Because prosecutors discovered the concerted effort to market Neurontin for off-label uses, the 5/13/04 settlement imposed a \$240 million criminal fine for violations of the FDCA. Warner-Lambert also pled guilty to two felonies. This fine was the second largest criminal fine ever imposed in a health care fraud prosecution at the time. Warner-Lambert also paid \$83.6 million and \$68.4 million, respectively, to settle civil violations of the False Claims Act as damages suffered by the federal and the 50 states' portions of the Medicaid programs. Warner-Lambert further paid \$38 million to settle civil violations of consumer protection statutes in all 50 states and D.C.

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41. As part of that settlement, Pfizer agreed to a corporate compliance program. According to the 5/13/04 DOJ press release:

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*Pfizer Inc*, Warner-Lambert's parent company, ***has agreed to comply with the terms of a corporate compliance program***, which will ensure that the changes Pfizer Inc made after acquiring Warner-Lambert in June 2000, are effective in training and supervising its marketing and sales staff, and ***ensures that any future off-label marketing conduct is detected and corrected on a timely basis***.

42. Even though the Neurontin settlement agreement specified that the illegal off-label marketing of Neurontin was conducted at Warner-Lambert before Pfizer acquired that company, Pfizer itself was required to execute the CIA to prevent illegal off-label marketing at Pfizer going forward.<sup>3</sup> The CIA imposed a Compliance Program which required Pfizer to: (i) appoint a Compliance Officer and a Deputy Compliance Officer who are members of senior management; (ii) form a Compliance Committee comprised of the Compliance Officer and other members of

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<sup>3</sup> The full text of 2004 CIA Pfizer entered into as part of the Neurontin settlement can be found at Ex. A.

<sup>617336\_2</sup> D\* = Defendants admitted certain facts in connection with this paragraph in their Amended Answer, and those admissions are incorporated by reference here.

senior management; (iii) establish a Code of Conduct, known as Pfizer's Policies or Blue Book, requiring Pfizer's commitment to abide by federal healthcare program rules and FDA requirements *"including its commitment to comply with all government contracting requirements and to market, sell, and promote its products in accordance with such requirements"* and requiring Pfizer to develop a mechanism for reporting violations of federal healthcare program rules and FDA requirements within the Company; (iv) implement policies and procedures to address, among other items, *"methods for selling, marketing, promoting, advertising, and disseminating information about off-label uses of Pfizer's products in compliance with all applicable FDA requirements"*; and (v) train and educate Pfizer employees how to comply with *"all applicable FDA requirements regarding the proper methods for selling, marketing, promoting, and advertising Pfizer's products, and disseminating information about the off-label uses of Pfizer's products including, but not limited to, the requirements of the Federal Food, Drug, and Cosmetic Act and FDA regulations."*

43. The CIA was very specific about senior management's responsibilities to monitor and report off-label marketing. The CIA required that Pfizer maintain a Disclosure Program to enable individuals to disclose any issues with "Pfizer's policies, conduct, practices, or procedure with respect to [any] Federal health care program requirements or FDA requirements believed by the individual to be potential violation of criminal, civil, or administrative law." Further, under the CIA, an internal review of the allegations was required where they were sufficiently specific to determine the appropriateness of the conduct and provided an opportunity for corrective action. The Compliance Officer (defendant Kindler, and later defendant Waxman) was charged with ensuring that a "disclosure log" be maintained that included a record and summary of each disclosure

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received, the status of any internal review and any corrective action taken in response to any internal review.

44. The CIA also required that the Compliance Officer and Deputy Compliance Officer make, at minimum, semi-annual reports regarding compliance matters directly to Pfizer's Board and charged these individuals as "*responsible for monitoring the day-to-day compliance activities* engaged in by Pfizer as well as for [the CIA's] reporting obligations." It mandated that a Compliance Committee consisting of members of senior management, such as senior executives of "internal audit, regulatory affairs, sales, marketing, personnel and operations," be maintained to "support the Compliance Officer in fulfilling his/her responsibilities," including "*monitoring of internal and external audits and investigations.*" Further, the CIA required an annual report to the OIG certified by the Compliance Officer that Pfizer is in compliance with the requirements of the CIA.

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45. As General Counsel, defendant Kindler oversaw Pfizer's negotiation and eventual settlement for unlawful off-label marketing of Neurontin. As it was negotiating and executing the CIA, the Company was contemporaneously flouting the very law defendants agreed Pfizer would strictly adhere to and continued to do so after the agreement was penned. In fact, defendants were, at the very moment that they entered the 2004 CIA, actively promoting drugs for off-label indications to the tune of billions of dollars (and millions of dollars in compensation for defendants).

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46. Defendants are well aware that physicians rely on Pfizer to comply with the law. Defendant McKinnell wrote in his book "A Call to Action" that "[d]octors, who are too busy to read all the literature on new drugs, value the briefings they receive[] from company representatives." He further admits that the "bulk of the pharmaceutical industry's 'marketing' budgets go to supporting professional representatives charged with the task of informing physicians about the products they

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represent.” To that end, “[e]xperience shows that face-to-face talks to doctors are more effective than printed information in getting doctors . . . to consider prescribing our products.” Pfizer took advantage of this knowledge by consistently formulating and implementing marketing strategies that were designed to foment doctors’ off-label drug use. Importantly, defendants knew throughout the Class Period that Pfizer faced a significant adverse material risk to its financial well-being, and even to its existence, as a result of the illegal promotion of drugs which they concealed from investors and for which they failed to reserve for in Pfizer’s financial statements filed with the SEC. Set forth below is a description of the widespread illegal marketing tactics employed by Pfizer.

47. **Bextra:** Bextra was launched in 4/02 and marketed under a co-promotion agreement between Pharmacia and Pfizer, even before Pfizer’s acquisition of Pharmacia. On 1/15/01, Pharmacia submitted an application to the FDA seeking approval of Bextra for the treatment of acute pain generally. On 11/16/01, *the FDA rejected the use of Bextra for acute pain generally*. The FDA only approved the use of Bextra to treat arthritis and menstrual discomfort. By no later than 6/03, Pfizer management was aware that members of Pfizer’s sales force were distributing materials promoting the off-label use of Bextra. Additional off-label marketing tactics Pfizer employed to increase Bextra sales were described by the many relators who filed *qui tam* actions,<sup>4</sup> and include:

- **Paying Physicians:** Relator Glenn DeMott (“DeMott”), a former Pfizer sales representative, describes a 5/28/03 “*Plan of Attack*” meeting, at which a district manager instructed Pfizer sales representatives to pay physicians to serve as speakers for off-label promotion to induce other physicians to place standing orders for Celebrex, and the effects of Celebrex and Bextra on bone healing and bone grafts;

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<sup>4</sup> Nine *qui tam* actions were filed and eventually resulted in the \$2.3 billion fine and penalties imposed on Pfizer. The *qui tam* actions allege additional detail beyond that set forth herein. If the Court requests additional details of Pfizer’s illicit off-label marketing practices during the Class Period, plaintiffs are willing and able to submit the pleadings in the *qui tam* cases.



- **Promoting Indications Off-Label:** DeMott also alleged that in 9/03 he and other sales representatives received materials created by Pfizer's Best Practices division in Portland, Oregon describing how to market Bextra and Celebrex off-label for pre-operative and post-operative treatments, not approved by the FDA. In 1/04, DeMott attended a Plan of Attack meeting where the 2004 Business Plan was distributed. *The Business Plan suggested that sales representatives can establish physician protocols for Bextra and Celebrex by calling anesthesiologists for the purpose of obtaining off-label sales for post-operative pain;*
- **Off-Label Protocols:** DeMott's notes taken during an 8/27/03 meeting with district manager and sales representatives confirm that a protocol was established for marketing 20 mg Bextra doses to the Columbus Blue Jackets, *an all-male professional hockey team* even though the only indication approved for 20 mg doses was for menstrual pain;
- **Misleading Safety:** Relator John Kopchinski ("Kopchinski"), a Pfizer Senior Specialty Representative, attached exhibits to his complaint, including Exhibit 4, a 1/27/03 PowerPoint presentation which instructs sales personnel to *mislead doctors concerning the safety of Celebrex and Bextra*. The presentation shows despite the limitations on Bextra's FDA approval, Pfizer viewed the entire "pain market" as a "huge opportunity" to sell Bextra. Further, Pfizer used "master visual aids" to sell Bextra, including for "acute pain";
- **Scripts with Unapproved Uses and Doses:** Kopchinski's Exhibit 9 is a script used as an aid to help Pfizer sales representatives market Bextra. The script was e-mailed to a number of sales groups at Pfizer. National sales director Mark Brown ("Brown") was carbon copied on the e-mail. *In a blatant contradiction of the FDA approved dosage for Bextra, the script suggests that sales representatives tell physicians that "Bextra provides the added spectrum of efficacy in that 20mg and 40mg doses are approved for more acute non-arthritic pain."* Bextra was never approved for use for acute non-arthritic pain or at 40 mg doses, as it was only approved for use at 20 mg doses for menstrual pain;
- **Sales Strategy on Unapproved Uses:** Exhibit 14 attached to the Kopchinski complaint includes an e-mail from Pfizer National Sales Director Brown to a number of Pfizer sales personnel. *The e-mail attaches a "review of the Oral Surgery study with Bextra." Brown informs the recipients that "[t]his is the study that Medical Inquiry sends out upon request." The FDA never approved the use of Bextra for oral surgery.* Further, under the "Sales Strategy" heading in the document is the statement, "[m]ake a point of how this study can help or hinder our sales efforts"; and
- **Halo Effect:** According to relator Kopchinski, Pfizer sales personnel were told to discuss only Celebrex safety for issues where Celebrex was purportedly better than Bextra, and to discuss only Bextra safety for the issues where Bextra was purportedly better than Celebrex. The purpose of the misleading presentation was to *confuse*

*doctors into thinking that the drugs were essentially the same and favorable safety information applied to both. The practice was commonly referred to at Pfizer as the “Halo” effect.*

48. In addition to the percipient witness accounts above, on 3/30/09 former Pfizer sales regional manager Mary Holloway (“Holloway”), who supervised 100 sales representatives and district managers, agreed to plead guilty to a federal charge based on her participation in the off-label marketing of Bextra. As part of the plea, Holloway agreed to the charges the government alleged in the Information, including:

- Holloway *trained and directed her sales team to seek unapproved written surgical and pain management protocols, standing orders and pathways from physicians, hospitals and other customers for use in pre- and post-operative surgical situations*;
- In or about 6/02, 11/03, and at other times, Holloway *instructed the sales force to send out unsolicited letters known as Medical Inquiry Letters* to groups of physicians who prescribed a lot of Vioxx to try to take market share. These letters were issued by Pharmco and purported to be responses to physicians’ unsolicited inquiries; and
- Holloway *circulated to her sales team an electronic template* of a hospital-wide pain management pathway *that provided for administration of Bextra for unapproved uses and at unapproved dosages* and to give instructions on how to prepare such pathways for distribution in hospitals and institutions.

49. The Holloway *sentencing memorandum confirmed that her actions were entirely “consistent with how Pfizer wanted her to promote and sell the product.”* According to the Holloway sentencing memorandum, “[t]he implementation of a marketing plan to obtain Bextra protocols and standing orders was *a company-wide initiative*.” As a result of these practices, annual sales of Bextra exceeded \$1.2 billion by 2004.

50. Ultimately, Pfizer was forced to remove Bextra from the market in 4/05 because of the increased risk of heart attacks and severe skin reactions resulting from its use. Despite Bextra’s removal, by the beginning of the Class Period, Pfizer had or was generating hundreds of millions of

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dollars of revenue from Bextra prescriptions written as a result of the Company's off-label marketing. Pfizer has admitted through its shell subsidiary, Pharmacia & Upjohn Company, Inc. ("Pharmacia & Upjohn") as part of its criminal plea, that the pecuniary or gross gain from the offense (*i.e.* off-label marketing) was \$664 million – a figure that was undoubtedly more. Defendants were aware from the Neurontin experience that Pfizer would be required to disgorge (i) ill-gotten gains with a multiplier for criminally promoting Bextra off-label, and (ii) amounts improperly paid by federal and state governments to Pfizer for off-label Bextra prescriptions via the Medicaid programs. Therefore, by the beginning of the Class Period, Pfizer had failed to reserve for these enormous contingent liabilities.

51. **Geodon:** Pfizer's unlawful promotion of Geodon began in 1/01 and continued through at least the end of 2007. Pfizer received FDA approval to market Geodon for schizophrenia, manic bipolar episodes and schizophrenia-related intramuscular pain relief only. Despite this approval, Pfizer marketed the drug for multiple off-label indications including depression, mood disorder, anxiety, aggression, dementia, and attention deficit hyperactivity disorder, and for unapproved patients (pediatric and adolescent patients) and at unapproved dosages. As a result of Pfizer's illegal marketing of Geodon, its revenue grew from \$150 million in 2001 to over \$850 million in 2007. Examples of Pfizer's promotion of Geodon off-label include:

- Corporate Sanctioned Illegal Marketing Scheme:** According to the *qui tam* complaint filed by Mark R. Westlock ("Westlock"), a Pfizer District Sales Manager, after only tallying up \$150 million in Geodon sales for 2001 and \$128 million for the first three quarters of 2002, in 11/02, ***the head of Pfizer's Geodon marketing conducted a national sales meeting*** attended by Pfizer sales managers, including district managers, regional medical research specialists and VPs from Pfizer corporate sales, ***at which he gave a presentation directing Pfizer's sales force to promote Geodon for a host of unapproved uses, including borderline personality disorder, depression, obsessive compulsive disorder, post traumatic stress disorder, dementia in the elderly, bipolar mania, bipolar maintenance and pediatric/adolescent conduct disorders. Thereafter, the unapproved uses were cited in Pfizer-sponsored literature and by Pfizer-sponsored speakers;***

- **Sponsored Speakers:** Westlock's complaint explains that the Pfizer Field Guide, its compliance "bible," provides that "Pfizer is held responsible for the conduct and content of its promotional speaker programs." He explains that ***Pfizer recruited a nationwide network of paid speakers to promote Geodon***, tracked each speaker's effectiveness (including each speaker's off-label presentations) and provided lists of these speakers to Pfizer's sales force. Westlock explains that one such speaker was Dr. Neil S. Kaye, who conducted hundreds of speeches promoting Geodon off-label wherein he was paid up to \$4,000 a day plus expenses. He was such a frequent promoter that Pfizer paid for him to use his own private helicopter to give speeches and a Pfizer V.P. had to approve his payments. Another speaker, Dr. M. Michael Ishii, blatantly included a slide entitled "Geodon Applications: Indication and Off Label" discussing a myriad of off-label uses for Geodon;
- **Off-Label Materials:** Westlock further explained that documents such as the one entitled "Neil Kaye, MD Geodon Take Home Selling Points" summarizing Dr. Kaye's ***off-label presentation*** for such unapproved uses as borderline personality disorder, dementia and major depression, were provided to thousands of sales representatives;
- **Regional Medical Research Specialists ("RMRS"):** According to Westlock, in an end-run around to the sales representatives' duty to promote Geodon on-label, ***RMRSs regularly accompanied Pfizer sales representatives to promote off-label use of Geodon***. For example, RMRS Dr. Barry Herman, in approximately 5/03, e-mailed a Pfizer Regional Sales Manager indicating that all "influentials" should be referred to him. Pfizer recognized Dr. Herman for his advocacy that increased Geodon's market share. Another example provided by Westlock, was RMRS Dr. Douglas Geenens, a child psychiatrist, who in 11/06, was asked to speak at a Pfizer sales meeting (known at Pfizer as ***Plan of Attack meetings***) where he showed slides and discussed a host of non-approved uses, including "conjectural indications," such as autism, depression, bipolar disorder, as well as unapproved use of Geodon for children. Dr. Geenens gave 75 to 125 talks for Pfizer in 2006 primarily on Geodon at which he readily promoted off-label uses. He received approximately \$150,000 for these talks;
- **Use of Non-Profits as a Trojan Horse:** Westlock indicates that Pfizer used NAMI (National Alliance for the Mentally Ill) as a front to increase the market share of Geodon. By way of example, Pfizer paid for Dr. Darrin Friesen to speak at a NAMI workshop on the advances of the treatment of schizophrenia and the results of the Clinical Antipsychotic Trials of Intervention Effectiveness ("CATIE") trial. Westlock explains that Dr. Friesen was a child psychiatrist and the CATIE trial was an adult trial, so Dr. Friesen was not qualified to speak on the trial. Further, Westlock explains that the real reason Pfizer paid for Dr. Friesen's speech was to ***secure continued heavy usage of Geodon*** by Dr. Friesen for his child and adolescent patients. Further still, the speech Dr. Friesen actually gave (paid for by Pfizer) was ***"little more than a Geodon promotional program to market Geodon off-label"***;
- **Promoting to Patients Where Use was Prohibited:** Westlock notes that Geodon has a ***black box warning against using it for treating elderly patients*** with dementia. Yet, Pfizer routinely promoted Geodon to doctors for this patient population to increase sales. For example, in 11/05 a Pfizer District Manager advised a group of 40-60 sales representatives at a ***Plan of Attack meeting*** that they could grow Geodon business by marketing ***in nursing homes***;

- **Marketing for Unapproved Dosages:** Geodon was approved for 80 mg doses, twice a day. *Despite Pfizer informing the FDA in 2000 that there could be adverse events if Geodon were used in excess of 160 mg a day and receiving an FDA warning letter on 9/3/02 for minimizing the safety risks regarding Geodon to cause QT prolongation and sudden death, as early as 2002 Pfizer began regularly promoting the dosing of Geodon well beyond the approved amount;* and
- **Unsubstantiated Comparison Claims:** On 8/17/06, 90 sales representatives received a voice message from a Pfizer Regional Manager telling them to use the “*compare and win strategy*” – to compare Geodon to a Bristol Myers Squibb product, Abilify, even though Pfizer lacked any clinical data to support the comparison. A few months later, in 11/06, the *Plan of Attack meeting* at Pfizer was called “*Competing to Win.*” Materials were provided to Pfizer sales force comparing Geodon to its competitors (e.g., Seroquel, Zyprexa, Risperdal, Abilify). These materials *contained unsubstantiated comparisons and also promoted Geodon for uses, such as bipolar maintenance, for which it was not approved.*

52. By the end of 2007, Pfizer had earned tens, if not hundreds, of millions of dollars via the illegal off-label promotion of Geodon and failed to reserve for the fines and penalties that would be assessed for this conduct or disclose to investors that the Company’s financial condition was marred by Pfizer’s unlawful off-label marketing of its drugs.

53. **Zyvox:** From 1/01 until late 2/08, Pfizer illegally promoted Zyvox for a variety of off-label conditions including infections caused by MRSA generally whereas the drug was only approved to treat certain MRSA infections. Further, Pfizer illegally promoted Zyvox as more effective than vancomycin during the Class Period even though the Company received the 2005 FDA Warning Letter specifically warning Pfizer not to market the drug as more effective than vancomycin. Pfizer continued to illegally promote the drug as more effective than vancomycin during the Class Period even though Pfizer agreed to stop marketing Zyvox in response to the 2005 FDA Warning Letter and vancomycin was much cheaper (\$18 versus \$150 per dose) and proven to be more effective than Zyvox. Pfizer accomplished its off-label marketing of the drug by offering and paying illegal remuneration to health care professionals to induce them to promote and prescribe Zyvox. As a result Zyvox’s annual sales grew from \$181 million in 2003 to more than \$900 million

in 2007. *Qui tam* relator Ronald Rainero (“Rainero”), a former Pfizer District Manager, described Pfizer’s practices as including:

- **Direct Promotions Off-Label:** Although *Zyvox was only indicated to treat pneumonia and simple skin infections, Pfizer directed its Zyvox sales force to call on surgeons and cancer hospitals to promote the drug.* For example, a 3/28-30/07 sales meeting at the Kingsmill Resort & Conference Center in Williamsburg, Virginia featured a session titled “Selling in Cancer Centers”; and
- **Marketing for Unapproved Uses:** *Despite the fact that Zyvox’s FDA approved label does not contain an indication for CA-MRSA, a Pfizer document titled “Zyvox empiric treatment – The Way to \$567 million” directed sales representatives to “reinforce Zyvox as the clear choice for empiric use for MRSA infection.”* Rainero also describes that a 1/27/07 e-mail indicates that at the January Plan of Attack meeting at Pfizer’s headquarters the strategy discussed for promoting Zyvox was to position “Zyvox as the clear choice for Empiric treatment” and “[r]einforce Zyvox use anywhere on the treatment continuum.”

54. Additionally, as part of the \$1.3 billion plea agreement by Pfizer’s subsidiary Pharmacia & Upjohn with the DOJ regarding Zyvox, “Pharmacia expressly and unequivocally admits that it knowingly, intentionally and willfully committed the crime charged in the attached Information and is in fact guilty of the offense, and agrees that it will not make any statements inconsistent with this explicit admission.”

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55. Further, in connection with Pfizer’s civil settlement for illicit sales practices, Pfizer admitted as “true and accurate” the following facts regarding its marketing of Zyvox:

- “On July 20, 2005, the FDA sent Pfizer the Warning Letter . . . regarding a journal advertisement for Zyvox. In this Warning Letter, the FDA stated that Pfizer’s advertisement misbranded Zyvox by making misleading and unsubstantiated implied superiority claims, claims that broadened the indications of Zyvox, and omitted important safety information”;
- “Despite notifying its sales force that it should cease using promotional materials that raised concerns of the type identified in the FDA Warning Letter, ***Pfizer did not provide adequate guidance to its sales force regarding what statements were permissible*** concerning data from head-to-head trials and retrospective analyses and what promotional statements were not permitted”;

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- “As a result, Pfizer’s sales personnel thereafter continued to make claims to physicians that Zyvox was superior to vancomycin for certain patients with MRSA, which included the claim that Zyvox would have a higher cure rate, and would save more lives, despite the fact that these claims were inconsistent with the FDA’s Warning Letter and Zyvox’s FDA approved label, and which were inconsistent with the manner in which Pfizer, after the receipt of the Warning Letter, agreed to present the clinical data cited by the FDA”;
- “Moreover, certain Pfizer sales managers, including a regional manager and a headquarters-based vice president, were aware of and, in certain cases, encouraged a sales message that Zyvox was superior to vancomycin for certain patients, despite their knowledge of the FDA Warning Letter and the issues it raised”;

56. **Lyrica:** Similar to Bextra, Geodon and Zyvox, Pfizer unlawfully promoted Lyrica, a drug referred to at Pfizer as the son of Neurontin. Beginning in 9/05 and continuing at least through the end of 10/08, Pfizer illicitly promoted Lyrica for a wide variety of off-label uses, including chronic pain, neuropathic pain, perioperative pain, migraines, sleep medication, mood improvement and anxiety. Pfizer had only obtained FDA approval for Lyrica to treat DPN/PHN and later fibromyalgia. Defendants’ unlawful promotion of Lyrica catapulted Lyrica’s sales growth by more than 700% from \$291 million in 2005 to over \$2.5 billion in 2008. Pfizer accomplished the off-label marketing of Lyrica by:

- **Unsubstantiated Comparisons:** According to *qui tam* relator Casey Schildauer (“Schildauer”), a Pfizer professional healthcare representative (“PHR”), on 5/9/06, at the Technology Park Hilton in Denver, Colorado, Pfizer’s senior sales management directed the Therapeutic Specialty Representatives to undertake a “***Compare and Win***” detail, comparing the purported efficacy of Keppra to Lyrica. According to the directives given, ***even though there had not been a head-to-head trial***, sales representatives were to create the impression for doctors that there had been such a head-to-head trial;
- **Promoting Unapproved Indicators:** *Qui tam* relator David Farber (“Farber”), a Pfizer PHR and later a specialty representative, described that on 10/12/05, Pfizer’s Rick Birch, Vice President of Arthritis, Pain and Metabolic-West, ***sent an e-mail to the entire Pfizer sales force, instructing the sales force to off-label market the Lyrica secondary endpoints for which it was not approved***. Copied on the Rick Birch e-mail are numerous members of senior management in the Pfizer Sales Division, including Carl D. Wilbanks, Executive Vice President of Sales;



- **Promotional Material with Unsubstantiated Comparisons:** In 9/06, Farber stated that Pfizer issued *promotional materials comparing gabapentin and Lyrica*, and included reprints of clinical studies for each drug including a study which discussed Lyrica’s secondary endpoints even though Lyrica was not approved for these uses;
- **Solicitation of Physicians:** According to *qui tam* relator Robert A. Liter (“Liter”), a Pfizer PHR, during the 9/05 National Sales meeting in Anaheim, California, *the sales representatives were encouraged to improperly promote Lyrica*, including to directly solicit physicians to prescribe Lyrica for off-label uses; use unsubstantiated scientific reports and comparative studies to promote the sale of Lyrica for off-label uses; and make false statements to physicians and pharmacists concerning the efficacy and safety of Lyrica for off-label uses; and
- **Unbiased Solicitations:** On 11/1/05, at the Point-of-Action meeting with over 80 other Pfizer sales representatives and district managers, the Regional Sales Manager for Indiana and Kentucky, Steve Reese, urged all sales representatives who were present to “*send as many medical inquiries*” as possible on Lyrica, according to a relator.

57. By 3Q08, Pfizer had earned tens, if not hundreds, of millions from the off-label promotion of Lyrica and failed to reserve for the fines and penalties from Pfizer’s unlawful conduct or disclose the material adverse risk of their illegal marketing activities.

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#### DEFENDANTS ISSUED FALSE AND MISLEADING STATEMENTS THAT PFIZER LAWFULLY PROMOTED ITS DRUGS

58. **Pfizer’s Business Conduct:** Each of Pfizer’s Forms 10-K and annual proxy statements on Form 14A filed with the SEC during the Class Period on 3/1/06, 3/16/06, 3/1/07, 3/15/07, 2/29/08 and 3/14/08, reference Pfizer’s Policies, which assured investors that Pfizer conducted its business in a lawful and ethical manner. The Company’s annual proxy statements stated that “[a]ll of our employees, including our Chief Executive Officer, Chief Financial Officer and Principal Accounting Officer . . . , are required to abide by Pfizer’s Policies on Business Conduct *to ensure that our business is conducted in a consistently legal and ethical manner.*” The proxy statements further characterized the Policies as “form[ing] the foundation of a comprehensive process that includes compliance with all corporate policies and procedures” and directed investors

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to “[t]he full texts of both Pfizer’s Policies on Business Conduct and of the Code of Business Conduct and Ethics for our Directors are published on our website at [http://www.pfizer.com/about/corporate\\_governance/board\\_policies.jsp](http://www.pfizer.com/about/corporate_governance/board_policies.jsp).” Additionally, the Forms 10-K filed with the SEC directed investors interested in “[i]nformation relating to corporate governance” to Pfizer’s Policies.

59. When he was CEO, defendant McKinnell emphasized in the introduction to the Policies that ***“Pfizer truly stands apart. Pfizer is proud of our record on compliance. Compliance with all relevant statutes and rules is both the legacy of our 150-year history and one of our most important advantages.”*** He further confirmed that the Blue Book’s “policies and practices are the foundation of our drive to become the world’s most valued company.”

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60. The Pfizer Policies referenced in the Company’s annual proxy statements and Forms 10-K filed on 3/1/06, 3/16/06, 3/1/07, 3/15/07, 2/29/08 and 3/14/08 also emphasized that the Company had a ***“well-structured compliance system,”*** was specifically complying with applicable laws and FDA requirements, and did not engage in off-label marketing when exactly the opposite was true. Asserting that, ***“Pfizer is committed to full healthcare law compliance globally,”*** Pfizer Policies assured investors that ***“[i]n the U.S., healthcare law compliance seeks to . . . eliminate the improper influence of financial incentives on medical judgment.”*** Pfizer’s Policies further confirmed that ***“[a]s Pfizer employee, you must comply with all laws relating to the conduct of business in the pharmaceutical industry.”***

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61. Significantly, the Policies referenced in Pfizer’s Class Period SEC filings affirmatively stated that Pfizer complied with FDA regulations, specifically referring to the promotion of Pfizer’s products as follows:

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***In a time when the news media is full of stories of business leaders and companies whose actions have engendered public suspicion and mistrust, Pfizer truly stands apart. Pfizer is proud of our record of compliance. Compliance with***

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*all relevant statutes and rules is both the legacy of our 150-year history and one of our most important advantages in global business.*

\* \* \*

*Pfizer observes all requirements of the U.S. Food and Drug Administration (FDA). . . .*

*While there are many aspects of FDA regulation to consider, **regulation of advertising and promotion of our products directly affects our customer relationships.** Therefore, **all employees are obligated to understand the basic rules Pfizer follows to ensure compliance with FDA law and regulations regarding labeling, promotion, off-label use, pharmaceutical samples, and adverse event reporting.***

62. Additionally, the Policies referenced in Pfizer's Forms 10-K and Forms 14A annual proxy statements filed with the SEC on 3/1/06, 3/16/06, 3/1/07, 3/15/07, 2/29/08 and 3/14/08 specifically addressed Pfizer's marketing practices. The Form 10-K and 14A confirmed that:

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***Pfizer will compete lawfully and ethically in the marketplace. We will act responsibly in our relationships with healthcare professionals, patients, hospitals, academics, governments, regulatory entities, partners, customers, suppliers, and vendors. . . .***

***To keep this promise to our customers and the marketplace, we will:***

- ***follow all antitrust and competition laws;***
- ***market products honestly, in accordance with laws and regulations;***
- ***gather business intelligence properly;***
- ***comply will all healthcare law obligations and generally respect our regulatory requirements . . . .***

\* \* \*

***At Pfizer, we are committed to fair competition. This means, among other things, abiding by all laws that apply to our marketing activities.** Under these laws it is illegal to use unfair methods of competition or unfair or deceptive acts or practices in commerce. **This prohibition includes, but is not limited to:***

- ***false or misleading advertising, or any other form of misrepresentation made in connection with sales.***



63. Pfizer's Policies referenced in Pfizer's Forms 10-K and Forms 14A annual proxy statements filed with the SEC on 3/1/06, 3/16/06, 3/1/07, 3/15/07, 2/29/08 and 3/14/08 also specifically addressed the anti-kickback laws, which defendants were then violating:

In the United States, *there is a special healthcare law (the Anti-kickback Law) that prohibits the offering of anything to a person that is intended to influence that person to recommend or purchase a healthcare products (including a prescription medication) or service that may be reimbursed by Medicare or Medicaid.* This is to ensure that a healthcare provider's decision about a choice of treatment or product for his or her patient not be influenced by motives of personal gain or enrichment. Please visit the Compliance web site at <http://compliance.pfizer.com> for more information.

64. On 5/15/05, Pfizer issued to the media its Global Policy on Interactions with Healthcare Professionals ("Global Policy"), which also falsely assured investors that Pfizer complied with healthcare program regulations and FDA rules as follows:

We recognize our interactions with healthcare professionals can give rise to apparent or actual conflicts of interest. We support the disclosure of financial and other interests and relationships that may create apparent or perceived conflicts of interest in research, education or clinical practice.

\* \* \*

We promote our medicines to healthcare professionals by providing substantiated information about the usage, safety, effectiveness and other aspects of the clinical profile of our medicines. . . . When describing the uses, effectiveness, safety and other aspects of our medicines, Pfizer colleagues and retained healthcare professionals must take care to avoid promoting *off-label* uses directly, indirectly or through third parties.

\* \* \*

In no instance will Pfizer provide financial support as an inducement for a healthcare professional to use, prescribe, purchase or recommend a Pfizer product or to influence the outcome of a clinical trial.

65. **Internal Controls:** Accompanying each of the Forms 10-Q and 10-K filed with the SEC during the Class Period were certifications executed by Pfizer executives which falsely

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represented that Pfizer's financial statements fairly presented "in all material respects the financial condition [and] results of [Pfizer's] operations":

I, [defendant],<sup>5</sup> certify that:

1. I have reviewed this report on [Form 10-Q/Form 10-K] of Pfizer Inc.;
2. Based on my knowledge, ***this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading*** with respect to the period covered by this report;
3. ***Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations*** and cash flows of the registrant as of, and for, the periods presented in this report;
4. ***The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures*** (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) . . . for the registrant and have:

(a) ***Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;***

\* \* \*

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most

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<sup>5</sup> Defendants McKinnell and Levin signed the certifications attached to Pfizer's 2005 Form 10-K and 1Q06 Form 10-Q; defendants Kindler and Levin signed the certification attached to Pfizer's 2Q06, 3Q06, 1Q07 and 2Q07 Forms 10-Q and FY 2006 Form 10-K; and defendants Kinder and D'Amelio signed the certifications attached to Pfizer's 3Q07, 1Q08, 2Q08, 3Q08 and FY 2007 Form 10-K.

recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. ***The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):***

(a) ***All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting*** which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) ***Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.***

66. On 4/2/07, Pfizer issued a release announcing that two subsidiaries of Pharmacia had reached settlements of \$34.7 million to "resolve . . . improper activities prior to acquisition by Pfizer," relating to Genotropin. While continuing to conceal the far more egregious off-label marketing campaigns related to Bextra, Lyrica, Geodon and Zyvox, defendants stated that "Pfizer discovered and promptly reported subsidiary's off-label marketing of Genotropin to Justice Department, other agencies."

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67. The 4/2/07 release also falsely assured investors that this \$34.7 million settlement was an isolated incident and that Pfizer's "internal controls" prevented such practices from occurring at Pfizer. According to defendant Waxman:

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***"Pfizer's marketing and promotion practices are not involved in the settlement. The company has internal controls to guard against these types of practices."***

68. ***Legal Proceedings and Contingencies:*** Pfizer's discussion of Legal Proceedings and Contingencies as well as Government Investigations and Requests for Information in each of the Forms 10-K (2005-2007) and Forms 10-Q (1Q06-3Q08) filed during the Class Period were each

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false and misleading when made.<sup>6</sup> Each of the SEC filings was prepared, reviewed and/or authorized by defendants, and concealed Pfizer's unlawful promotion of Geodon, Lyrica and Zyvox, its illegal kickbacks to doctors to promote drugs and its massive liability for the off-label promotion of Bextra.

69. For example, Pfizer's FY 2005 Form 10-K filed with the SEC on 3/1/06 omitted Pfizer's material adverse risk facing Pfizer for its illegal conduct, stating:

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#### **Legal Proceedings**

We and certain of our subsidiaries are involved in various patent, product liability, consumer, commercial, securities, environmental and tax litigations and claims; government investigations; and other legal proceedings that arise from time to time in the ordinary course of our business. Litigation is inherently unpredictable, and excessive verdicts do occur. Although we believe we have substantial defenses in these matters, we could in the future incur judgments or enter into settlements of claims that could have a material adverse effect on our results of operations in any particular period.

\* \* \*

#### **Contingencies**

We and certain of our subsidiaries are involved in various patent, product liability, consumer, commercial, securities, environmental and tax litigations and claims; government investigations; and other legal proceedings that arise from time to time in the ordinary course of our business. We record accruals for such contingencies to the extent that we conclude their occurrence is probable and the related damages are estimable.

\* \* \*

#### **Legal Proceedings and Contingencies**

We and certain of our subsidiaries are involved in various patent, product liability, consumer, commercial, securities, environmental and tax litigations and

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<sup>6</sup> Copies of the precise language used with respect to the status of Pfizer's Legal Proceedings and Contingencies in each of these SEC filings can be found at <http://www.sec.gov/cgi-bin/browse-edgar?action=getcompany&CIK=0000078003&owner=exclude&count=40>.

claims; government investigations; and other legal proceedings that arise from time to time in the ordinary course of our business. We do not believe any of them will have a material adverse effect on our financial position.

\* \* \*

#### **F. Government Investigations and Requests for Information**

\* \* \*

We received requests for information and documents from the Department of Justice in 2003 concerning the marketing of Genotropin as well as certain managed care payments, and in 2005 concerning certain physician payments budgeted to our prescription pharmaceutical products.

In 2003 and 2004, we receive requests for information and documents concerning the marketing and safety of Bextra and Celebrex from the Department of Justice and a group of state attorneys general. In 2005, we received a similar request from the staff of the Securities and Exchange Commission.

\* \* \*

We received a letter from the Office of the Attorney General of the State of New York in 2004 requesting documents and information concerning clinical trials of certain of our pharmaceutical products for indications other than those approved by the FDA and concerning possible promotion of those products for such indications. We also received a letter from the Office of the Attorney General of the State of Connecticut in 2004 requesting similar materials concerning Zoloft.

70. Pfizer's 2006 Form 10-K filed with the SEC on 3/1/07 likewise concealed Pfizer's unlawful and criminal promotion of Geodon, Lyrica and Zyvox, its illegal kickbacks to doctors to promote drugs and its massive liability for the off-label promotion of Bextra. Rather, the 2006 Form 10-K misleadingly stated:

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Since 2003, we have received requests for information and documents concerning the marketing and safety of Bextra and Celebrex from the Department of Justice and a group of state attorneys general. We have been considering various ways to resolve these matters.

Since 2005, we have received requests for information and documents from the Department of Justice concerning certain physician payments budgeted to our prescription pharmaceutical products.

71. On 11/5/07 Pfizer filed its 3Q07 Form 10-Q with the SEC. The Form 10-Q continued to mislead investors regarding Pfizer's illegal off-label marketing and the criminal and civil liability Pfizer faced as a result, stating:

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As previously reported, since 2003 we have received requests for information and documents in connection with potential claims concerning the marketing and safety of Bextra and Celebrex from a group of state attorneys general. We believe that we have strong defenses to any potential claims that may be asserted by members of the attorney general group, and we continue to explore various ways to resolve any such potential claims.

72. On 2/29/08 Pfizer filed its 2007 Form 10-K with the SEC. The Form 10-K continued to mislead investors about Pfizer's off-label marketing activities stating:

The Department of Justice continues to actively investigate the marketing and safety of our COX-2 medicines, particularly Bextra. The investigation has included requests for information and documents. We also have received requests for information and documents in connection with threatened claims concerning the marketing and safety of Bextra and Celebrex from a group of state attorneys general. We have been considering various ways to resolve these matters.

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73. On 8/8/08 Pfizer filed its 2Q08 Form 10-Q. In furtherance of defendants' wrongful scheme Pfizer continued to conceal its unlawful marketing practices. With respect to the active DOJ investigation, where settlement negotiations had been underway for more than two months, the Form 10-Q disclosed the following:

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The Department of Justice continues to actively investigate the marketing and safety of our COX-2 medicines, particularly Bextra, and more recently has begun to investigate the marketing of certain other drugs. These investigations have included requests for information and documents. *We have been considering various ways to resolve the COX-2 matter, which could result in the payment of a substantial fine and/or civil penalty.*

74. On 10/17/08, Pfizer issued a release regarding the \$894 million settlement of personal injury claims related to Bextra and Celebrex, a class action consumer fraud case involving Bextra and Celebrex, and claims brought by 33 states and the District of Columbia relating to Bextra promotional practices for \$60 million. The press release provided “*it puts the substantial*

**majority of the civil litigation the company is facing with regard to [Celebrex and Bextra] behind us,’ said Amy Schulman, senior vice president and General Counsel of Pfizer. ‘And I think the view was, putting these matters substantially behind us was the right thing to do.’”**

75. Following the press release, the media reported on the settlement, noting:

- *Forbes* (10/17/08) – “Pfizer said it expects this all to be behind it by the end of the year.”
- *Wall Street Journal* (10/18/08) – Credit Suisse analyst Catherine Arnold said in a *Wall Street Journal* article that “[i]t’s strategically disappointing they’re writing a check for \$900 million for a legal settlement [rather] than for buying up assets, which is what they need for future growth.”
- *States News Service* (10/22/08) – “Attorney General Says Connecticut Will Receive \$1.7 million Under Pfizer Settlement . . . ‘Pfizer pumped profits by suppressing facts – dangerously disregarding patient safety by promoting drugs for unapproved uses.’”
- *Global Insight* (10/20/08) – “This allows the firm to look ahead to potential lower litigation costs in forthcoming years, and focus on bolstering its new products pipeline, with revenues expected to take a hit as the patent term of its blockbuster product Lipitor (atorvastatin) comes to a close.”

76. On 11/7/08 Pfizer filed with the SEC its Form 10-Q for 3Q08, which discussed the Celebrex and Bextra settlement but continued to conceal Pfizer’s enormous liability for off-label marketing of Bextra, Lyrica, Geodon or Zyvox and the enormous liability Pfizer faced, including exclusion from federally funded health care programs, because of its unlawful off-label promotion of drugs:

A. Product Litigation – Celebrex and Bextra

In October 2008, we reached agreements in principle to resolve the pending U.S. consumer fraud purported class action cases and more than 90% of the known U.S. personal injury claims involving Celebrex and Bextra, and ***we reached agreements to resolve substantially all of the cases and claims of state attorneys general involving Celebrex and Bextra.*** In connection with these actions, we recorded litigation-related charges of approximately \$900 million in Other

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D\* = Defendants admitted certain facts in connection with this paragraph in their Amended Answer, and those admissions are incorporated by reference here.

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(income)/deductions - net in the third quarter of 2008. Virtually all of this amount is included in Other current liabilities on the condensed consolidated balance sheet as of September 28, 2008.

\* \* \*

The settlement agreements and agreements in principle and the charge to earnings do not apply to the other previously reported actions relating to Celebrex and Bextra, including the purported class actions alleging the violation of federal securities laws, the purported derivative actions alleging breach of fiduciary duty and the purported class actions alleging the violation of the Employee Retirement Income Security Act of 1974 (ERISA), nor do they apply to the pending investigation by the Department of Justice of the marketing of the Company's COX-2 medicines, particularly Bextra. The Department of Justice investigation could result in the payment of a substantial fine and/or civil penalty.

77. The foregoing statements in ¶¶58-76 regarding Pfizer's conduct, internal controls and disclosures were false and misleading when made. The true facts which were known or recklessly disregarded by defendants were that:

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(a) Pfizer's Policies referenced in its SEC filings throughout the Class Period and the Global Policy were misleading in that Pfizer was not, in fact, complying with federal health care statutes and FDA regulations prohibiting off-label marketing of drugs. Instead, defendants were employing (or had employed) a myriad of undisclosed illegal marketing tactics to promote unapproved uses of Bextra (¶¶47-50), Geodon (¶¶51-52), Zyvox (¶¶53-55) and Lyrica (¶¶56-57). For example, Pfizer's illegal marketing practices included: (i) paying-off physicians with lavish trips with the knowledge that these doctors would attend presentations and drive off-label sales of Bextra (¶47); (ii) paying doctors thousands of dollars to promote Geodon off-label (¶51); (iii) continuing to promote Zyvox as more efficacious than vancomycin (which cost substantially less than Pfizer's drug) in violation of the 2005 FDA Warning Letter (¶53); and (iv) promoting unsubstantiated head-to-head comparisons of Lyrica with other drugs (¶56);



(b) The 2004 CIA mandated compliance with the law and that the institution of policies to ensure that Pfizer's business was "conducted in a consistently legal and ethical manner." Defendants assured investors that "Pfizer observes all requirements of the FDA" and that it committed to the "prohibition" against "false or misleading advertising." Defendants McKinnell, Levin, D'Amelio and Kindler also certified that various Pfizer Class Period financial statements "did not contain any untrue statements." In contrast to these affirmative statements, defendants knew or were deliberately reckless in not knowing of Pfizer's systemic disregard for the very laws they falsely claimed Pfizer was in compliance with. Defendants were well aware that Pfizer faced a material adverse risk to its bottom line and future well-being, including debarment as well as massive fines and penalties for violating health care statutes and FDA rules as a result of the negotiations leading up to and execution of the CIA. ¶¶37-46;

(c) Despite the Company's own internal Policies, the reporting procedures mandated by the CIA requiring employees to report off-label promotion, and the fact that employees did report such violations to senior management, defendants nonetheless falsely assured investors that the adequacy of Pfizer's controls, including its "compliance system," prevented any such unlawful activity at Pfizer. Several former Pfizer employees, including regional manager Holloway, have detailed how off-label marketing practices were not isolated and were communicated up the chain via the Compliance protocol. ¶¶121-122;

(d) Defendants concealed Pfizer's participation in off-label marketing campaigns and misrepresented the nature and the extent of the DOJ's investigation into Pfizer's off-label marketing of drugs Bextra, Geodon, Lyrica and Zyvox. Instead, defendants crafted a few purported "disclosures" which were themselves misleading because they concealed the material adverse risk to Pfizer's financial statements and its ongoing business as a result of their pervasive illegal marketing

tactics. Defendants were well aware, based on Pfizer's prior experiences that the Company's unlawful off-label promotions exposed Pfizer to billions of dollars of criminal fines and civil penalties. ¶¶37-46. Therefore, defendants' purported disclosures of "requests for information" and "investigations" were materially false and misleading because defendants had full knowledge of the extent and massive exposure the Company faced, including debarment; and

(e) Even though, as part of a CIA Pfizer signed in 2002, Pfizer had agreed to detect and prevent payments to healthcare professionals to influence their product selections, defendants secretly continued their ongoing violations of the anti-kickback laws through 2004. Pfizer made illegal payments for speaker programs, mentorships, preceptorships, entertainment, travel and meals, and in cash to numerous healthcare professionals in exchange for the promotion and prescribing of drugs including Aricept, Celebrex, Lipitor, Norvasc, Relpax, Viagra, Zithromax, Zolof and Zyrtec. Thus, defendants' public assurances that Pfizer was committed to "abiding by all laws that apply to our marketing activities" and "[i]n no instance will Pfizer provide financial support as an inducement for a healthcare professional" were false and misleading.

**PFIZER'S CLASS PERIOD FINANCIAL STATEMENTS WERE  
MATERIALLY MISSTATED IN VIOLATION OF GAAP**

78. Defendants caused Pfizer to issue false and misleading financial results in Pfizer's earnings releases issued during the Class Period (1/19/06, 4/19/06, 7/20/06, 10/19/06, 1/22/07, 4/20/07, 7/18/07, 10/18/07, 1/23/08, 4/17/08, 7/23/08 and 10/21/08) and SEC filings (4Q05, 1Q06, 2Q06, 3Q06, 1Q07, 2Q07, 3Q07, 1Q08, 2Q08 and 3Q08 Forms 10-Q and FY05, FY06 and FY07 Forms 10-K), including Pfizer's net income and diluted earnings per share ("EPS"), as follows:

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*(In millions of \$ except for EPS)*

<b>Fiscal Period</b>	<b>Other Income/ (Other Deductions) - Net</b>	<b>Net Income</b>	<b>Diluted EPS</b>	<b>Filed with the SEC</b>
4Q 2005	\$321	\$2,732	\$0.37	3/1/06
<b>Full Year 2005</b>	<b>(\$347)</b>	<b>\$8,085</b>	<b>\$1.09</b>	<b>3/1/06</b>
1Q 2006	\$272	\$4,111	\$0.56	5/8/06
2Q 2006	\$359	\$2,415	\$0.33	8/11/06
3Q 2006	\$343	\$3,362	\$0.46	11/3/06
4Q 2006	(\$70)	\$9,449	\$1.30	3/1/07
<b>Full Year 2006</b>	<b>\$904</b>	<b>\$19,337</b>	<b>\$2.66</b>	<b>3/1/07</b>
1Q 2007	\$402	\$3,392	\$0.48	5/4/07
2Q 2007	\$487	\$1,267	\$0.18	8/6/07
3Q 2007	\$260	\$761	\$0.11	11/5/07
4Q 2007	\$610	\$2,724	\$0.40	2/29/08
<b>Full Year 2007</b>	<b>\$1,759</b>	<b>\$8,144</b>	<b>\$1.18</b>	<b>2/29/08</b>
1Q 2008	\$333	\$2,784	\$0.41	5/2/08
2Q 2008	\$167	\$2,776	\$0.41	8/8/08
3Q 2008	(\$721)	\$2,278	\$0.34	11/7/08
4Q 2008 <sup>7</sup>	(\$1,811)	\$266	\$0.04	2/27/09
<b>Full Year 2008</b>	<b>(\$2,032)</b>	<b>\$8,104</b>	<b>\$1.20</b>	<b>2/27/09</b>

79. Pfizer's reported net income and diluted EPS as set forth in ¶¶78 above were materially false and misleading for the following reasons:

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(a) Net income and diluted EPS each incorporate not only revenue earned by a company, but also its costs and liabilities. Pfizer's Class Period financials failed to properly account for the probable, or even reasonably possible, liabilities known to defendants as a result of Pfizer's unabated off-label marketing of four of its blockbuster drugs as described in ¶¶47-57, in violation of GAAP. Thus, Pfizer's reported net income and diluted EPS were artificially inflated during the Class Period;

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<sup>7</sup> Pfizer's 4Q08 financial results are included in this chart for comparative purposes only.

(b) Pfizer represented that its financial statements complied with GAAP.<sup>8</sup> GAAP requires the accrual of a loss contingency by a charge to income, (in the case of Pfizer the charge would be in the form of a loss reserve) if, at the time that a financial statement is issued, it is probable that a contingent liability or potential loss has been incurred, and the loss can be reasonably estimated. SFAS No. 5, ¶8.<sup>9</sup> Defendants knew of Pfizer's exposure to increasing fines and penalties associated with off-label marketing because of, *inter alia*: (i) Pfizer's receipt of such fines and penalties less than two years prior to the Class Period in connection with the Neurontin settlement; (ii) its prior experience with government investigations; and (iii) its knowledge thereof of federal statutes from which any such fine or penalty would be derived. Further still, defendants knew of internal compliance complaints regarding off-label marketing and violations of the CIA as well as the DOJ investigation into the marketing and sale of Bextra by 2004 (¶¶12, 121). Thus, defendants were able to estimate the possible loss or range of loss and were required under GAAP to report this information in Pfizer's financial statements. For example, by the start of the Class Period, defendants should have reserved a minimum of \$1.8 billion in loss reserves related to its fraudulent

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<sup>8</sup> GAAP are those principles recognized by the accounting profession as the conventions, rules and procedures necessary to define accepted accounting practice at a particular time. SEC Regulation S-X (17 C.F.R. §210.4-01(a)(1)) states that financial statements filed with the SEC which are not prepared in compliance with GAAP are presumed to be misleading and inaccurate, despite footnote or other disclosure. Regulation S-X requires that interim financial statements must also comply with GAAP, with the exception that interim financial statements need not include disclosures, which would be duplicative of disclosures accompanying annual financial statements. 17 C.F.R. §210.10-01(a).

<sup>9</sup> On 6/30/09, the Financial Accounting Standards Board ("FASB") issued SFAS No. 168, "The FASB Accounting Standards Codification™ and the Hierarchy of Generally Accepted Accounting Principles – a replacement of FASB Statement No. 162." FASB Accounting Standards Codification™ ("ASC") became the source of authoritative U.S. accounting and reporting standards for nongovernmental entities, in addition to guidance issued by the SEC. These allegations use the historical references to U.S. GAAP, as such references existed during the Class Period.

marketing of Bextra. As for Geodon, Lyrica and Zyvox, defendants should have increased the reserves during the Class Period as the off-label practices of these drugs continued, with the Company reserving the full \$2.3 billion by 3Q08 at the latest. Instead, defendants misled investors by (i) not calculating and recording a contingent loss; and (ii) by not sufficiently disclosing that exposure until 1/09;

(c) At the very least, defendants should have disclosed that Pfizer continued to engage in off-label marketing and faced the potential for exclusion from federally funded healthcare programs and the associated financial consequences or a record-setting fine. GAAP (SFAS No. 5, ¶10) requires, at a minimum, that “*disclosure of the contingency shall be made* when there is at least a reasonable possibility that a loss or an additional loss may have been incurred.”<sup>10</sup> The disclosure “*shall indicate the nature of the contingency and shall give an estimate of the possible loss or range of loss or state that such an estimate cannot be made.*” (SFAS No. 5, ¶10). Nonetheless, in violation of SFAS No. 5, defendants failed to disclose that both prior to and during the Class Period, the Company engaged in an ongoing course of conduct designed to illegally promote the sale of Pfizer drugs, including Bextra, Geodon, Zyvox and Lyrica. As a result of defendants’ conduct, the Company submitted hundreds of millions of dollars in false or fraudulent claims to several federal healthcare programs, exposing the Company to billions of dollars of untold legal liability and potential exclusion from federally funded health care programs; (¶¶37-57)

(d) Additional GAAP provisions provide that pending or threatened litigation and actual or possible claims and assessments is a loss contingency under SFAS No. 5, ¶33, *that must be*

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<sup>10</sup> Under SFAS No. 5, ¶10, “reasonable possibility,” means the chance of the future event or events occurring is more than remote but less than likely.

*accrued for and/or disclosed in a company's financial statements.* In the case of an investigation by a governmental agency, if enforcement proceedings have been or are likely to be instituted, then a company should disclose the contingency and establish a reserve to cover the estimated potential loss. SFAS No. 5, ¶38. Defendants knew of the DOJ investigation of Bextra in 2004, and of the likelihood of enforcement proceedings for the pervasive off-label marketing of three additional blockbuster drugs – Geodon, Lyrica and Zyvox – beginning no later than fall 2006 (¶¶13, 121), but failed to accrue for or disclose the loss contingencies stemming from Pfizer's recidivist conduct;

(e) Further, Item 303 of Regulation S-K under the federal securities law (17 C.F.R. §229.303) imposes a disclosure duty “where a trend, demand, commitment, event or uncertainty is both [1] presently known to management and [2] reasonably likely to have material effects on the registrant's financial condition or results of operation.” Management's Discussion and Analysis of Financial Condition and Results of Operations, Release Nos. 33-6835; 34-26831; IC-16961. Pfizer's unabated off-label marketing of Bextra, Zyvox, Lyrcia and Geodon, after the 2004 CIA, created a trend and uncertainty known to management (*i.e.* the defendants) *vis-a-vis* the compliance programs and reporting structure required by the CIA, and set forth in Pfizer's internal policies. This trend and uncertainty was “reasonably likely” to have material negative consequences to Pfizer's financial condition and results of operation in the form of contingent liabilities (which Pfizer at no point reserved for), as well as the real possibility of debarment from government funded healthcare programs. Yet, defendants failed to disclose in violation of Item 303 of Regulation S-K to investors the known trends and uncertainty facing Pfizer.

80. Under GAAP and SEC standards, and as acknowledged by defendants in Pfizer's Forms 10-K filed during the Class Period, Pfizer's management is responsible for the preparation of Pfizer's financial statements, including the establishment and maintenance of adequate internal

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<sup>617336\_2</sup> D\* = Defendants admitted certain facts in connection with this paragraph in their Amended Answer, and those admissions are incorporated by reference here.

controls over financial reporting.<sup>11</sup> With respect to loss contingencies, Pfizer's management is responsible for the identification of any potential litigation, claims and assessments against the Company and the evaluation of and accounting for such claims and assessments. Defendants, Pfizer's management, knew of material risks and contingencies as a result of the CIA's mandate and Pfizer's own stated policies requiring that they monitor and be informed of illegal marketing. Nevertheless, defendants failed to accrue for such contingencies or sufficiently disclose the contingencies to investors.

**DEFENDANTS' ASSURANCES REGARDING PFIZER'S  
DIVIDEND PAYMENTS WERE FALSE AND MISLEADING**

81. On 3/5/08 defendants caused Pfizer to host numerous analysts at a Pfizer Analyst Meeting in order to assuage concerns about Pfizer's ability to continue its dividend payments. Having previously assured investors that Pfizer's strong operating cash flow would support Pfizer's dividend payments, defendant D'Amelio indicated that Pfizer would continue to pay its dividend "at least at current levels" absent "significant unforeseen events":

[Tim Anderson:] And then Frank's question about the dividend, you said maintain it at least at current levels, and I'm just wondering what time period you're referring to and specifically I'm alluding to the period at which Lipitor goes away and are you suggesting that it stays all the way through that cliff period?

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[D'Amelio:] *So on the dividend, the way I framed it was, I'll call it significant unforeseen events aside. So what's a significant unforeseen event? Something that's significant that I'll call it has a big impact on our operating cash flow, so that aside, our intention is to continue to fund the dividend at least at*

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<sup>11</sup> Pfizer also had no assurance from its auditors because in connection with the Company's audit of its financial statements and its internal control systems, Pfizer has adopted a reliance model with its external auditors whereby its external auditors would rely on the work of the Company's internal auditors and even Pfizer's management to a certain extent when conducting its audits.



*current levels, and that's going forward.* I said that was going forward in my comments.

82. Analysts at Credit Suisse reported on 10/21/08 that Pfizer reaffirmed its commitment to continued funding of the dividend “*at least* at current levels.”

83. The statements in ¶¶81-82 above were false and misleading because defendants knew at the time the statements were made, but concealed from investors, that substantial fines and penalties as a result of Pfizer’s off-label marketing campaigns of Bextra, Lyrica, Geodon and Zytov, as well as the illegal kick backs defendants had paid to physicians, would have a significant and foreseen impact on Pfizer’s cash-flow to the tune of more than \$2 billion. Further, defendants knew the importance of having enough U.S. cash on hand to the Company’s bottom-line because the dividend was paid from Pfizer’s U.S. funds. Without sufficient cash on hand in the U.S. to maintain the dividend, Pfizer would have to borrow money or repatriate off-shore cash, which would have adverse tax consequences on earnings.

#### DEFENDANTS’ STATEMENTS REGARDING REVENUE GROWTH AND PFIZER’S DRUGS’ EFFICACY WERE FALSE AND MISLEADING

84. *Growth Fueled by Drug Performance:* Throughout the Class Period, defendants repeatedly made false and misleading statements regarding the growth and success of its drugs, a performance that, unbeknownst to investors, was fueled by Pfizer’s illegal off-label marketing. The statements include, but not limited to:

- Release (1/19/06) – “*Geodon exhibited strong full-year growth*” and “*[i]ts balance of powerful efficacy and a favorable metabolic profile positions it for further growth.*”
- Release (4/19/06) – “*Pfizer expects that performance of key products – including . . . Lyrica, and Geodon – will continue to drive overall performance for Pfizer Human Health.*”
- Release (4/19/06) – “*Geodon growth is due to the improved perception among clinicians of its efficacy, increased benefits from optimal dosing, and its favorable metabolic profile, as confirmed by the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) trial.* As the

***only antipsychotic that demonstrates efficacy . . . positioned to allow psychiatrists to treat mental health ‘with the body in mind.’”***

- Deutsche Bank Securities 31st Annual Healthcare Conference (5/2/06) – ***“Geodon’s strong performance is due to the improved perception among clinician’s of its efficacy, increased benefits for optimal dosing and its favorable metabolic profile.”***
- Release (10/18/07) – ***“Lyrica’s growth continues to be fueled by strong efficacy as well as high patient and physician satisfaction in the marketplace.”***
- Release (10/21/08) – ***“We continue to deliver steady results this quarter, with many of our most important medicines performing well around the world, including Lyrica, . . . Zyvox and Geodon . . . .”***

85. Throughout the Class Period defendants repeated false and misleading statements about Geodon, Lyrica and Zyvox, and how these drugs sales would drive Pfizer’s growth. Plaintiffs attach as Ex. B the precise language of each statement plaintiffs allege to be materially false and misleading, and incorporate those statements by reference herein. Not only did defendants mislead physicians and patients about the efficacy and safety of their drugs to increase sales, they similarly misled investors about these very same issues by telling them that these drugs were performing well and to expect strong growth as a result. Pfizer’s growth was, in fact, fueled by defendants’ unlawful marketing campaigns including marketing these drugs for unapproved uses as follows:

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	Approved	Illegal Marketing Tactics
Geodon	Acute Manifestations of Schizophrenia Acute Manic or Mixed Episodes of Bipolar Disorder	depression bipolar maintenance mood disorder anxiety aggression dementia attention deficit hyperactivity disorder obsessive compulsive disorder autism post-traumatic stress disorder pediatric and adolescents unapproved dosages
Lyrica	DPN/PNP Fibromyalgia	chronic pain neuropathic pain perioperative pain

	Approved	Illegal Marketing Tactics
		migraine
Zyvox	Certain Infections Caused by MRSA	infections caused by MRSA generally in violation of the 2005 FDA Warning Letter prohibiting promotion of Zyvox as more effective than vancomycin

86. Because defendants concealed from investors that they actively promoted Pfizer's drugs for unapproved indications and for uses that were specifically banned by the FDA, defendants' affirmative statements regarding the efficacy, safety and performance of these drugs were materially false and misleading. As explained below, defendants knew but concealed from Class members that the performance of Pfizer's drugs, including reported revenues of more than \$9.7 billion during the Class Period for Geodon, Lyrica and Zyvox, included substantial revenues directly derived from unlawful off-label marketing. Defendants' affirmative statements misled investors into believing otherwise.

87. For example, each of defendants' statements between 2/10/06 and 12/31/07 about the growth of Geodon sales – “another fast-growing Pfizer product with plenty of growth potential left – Geodon,” “Geodon contributed strong revenue growth during the first quarter,” “ and [l]et's now look at Geodon, a growing success story” – were false and misleading because the growth was achieved through Pfizer's illegal off-label marketing. As explained in ¶¶51-52, the illegal off-label marketing of Geodon was rampant and included: encouraging sales personnel at a national sales meeting to promote Geodon for uses not approved by the FDA; paying speakers to promote off-label uses; encouraging the use of Geodon during Plan of Attack meetings for elderly patient populations, when Pfizer knew that Geodon had a black box warning for dementia; promoting Geodon for use in treating children for whom it was not approved; and making unsubstantiated head-to-head comparisons between Geodon and other drugs.

88. Not only did defendants encourage the use of Geodon off-label via Pfizer's salesforce, defendants also misrepresented the safety and efficacy of Geodon to investors. For example, defendants repeatedly misrepresented the results of the CATIE trial comparing five frequently used antipsychotic agents. In the 2/10/06 Pfizer Analyst Meeting (Ex. B at No. 4) defendants claimed that "Geodon was the only medicine of the five to effectively improve patients' psychiatric syndromes with comparable efficacy to established agents despite sub-optimal dosing while reducing weight, reducing cholesterol, reducing lipids and reducing measures of glucose." On the same day, 2/10/06, defendants McKinnell and Kelly made specific assurances that Pfizer's "current promotional materials" for Geodon were "clearly on label." These assurances were also false. Similarly, on 4/19/06 Pfizer issued a release (Ex. B at No. 11), stating that: "Geodon growth is due to the improved perception among clinicians of its efficacy, increased benefits from optimal dosing, and its favorable metabolic profile, as confirmed by the [CATIE] trial."

89. The CATIE trial actually revealed that Geodon was not more effective than the other anti-psychotic drugs to which it was compared. The drug did **not** prove itself more effective at higher doses. In fact, there was no proof that higher dosing of Geodon results in better outcomes for patients. Defendants' statements were materially misleading because they also ignored the increased risks of adverse consequences associated with higher dosing. Higher doses of Geodon increase the risk of extrapyramidal neurological problems, insomnia, internal restlessness, sudden death, tics, tardive dyskinesia and QTc prolongation with arrhythmogenic potential. In addition, the CATIE trial actually demonstrated that the drug was less effective than Zyprexa, and although it has a better profile in terms of weight gain and some metabolic indications when compared in particular to Zyprexa, Geodon continued to have serious problems causing anxiety, insomnia, elevations in glycosylated hemoglobin, neurological side-effects and overall clinical intolerability. Weight gain

was only *one* of the reasons individuals stop their antipsychotic medications. There were more significant reasons patients cease those medications, including akathisia, internal restlessness, sudden death, arrhythmias, dystonias, tardive dyskinesia, insomnia and excessive somnolence. Geodon caused each of these more significant side effects. Thus, defendants' statement that Pfizer grew market share for Geodon by increasing prescriptions for the treatment of schizophrenia and bipolar disorder because of the benefits of Geodon were false and concealed that Pfizer was actually growing market share for this drug by illegal off-label marketing.

90. In addition, defendants' statements regarding Lyrica falsely implied that its sales growth was organic, and failed to disclose that sales actually increased as a result of defendants' illicit off-label marketing of Lyrica between 2005 and the end of 10/08. Defendants told investors that "there are an extraordinary number of patients with neuropathic pain" that were responsible for "a lot of the rapid uptake in Lyrica" and that Lyrica had been "well-received by both physicians and patients, because of its ability to relieve debilitating neuropathic pain." See Ex. B at Nos. 3, 19.

Defendants were well aware, however, that Lyrica was approved only for pain associated with DPN and PHN, a much smaller market for Lyrica than the universal indications of neuropathic pain that defendants represented to investors. Pfizer later received approval for Lyrica to treat fibromyalgia. However, this market was also very small, and the physical symptoms associated with that disease do not relate to neuropathic pain. To increase profits, defendants illegally marketed Lyrica by several means as set forth in more detail above (¶¶56-57), which are incorporated by reference herein and include: (i) directly soliciting physicians to prescribe Lyrica for off-label uses; and (ii) sending unsolicited medical inquiries directly to physicians.

91. On 9/22/08 defendants told the market that they were differentiating Lyrica "based on its rapid onset of action, persistence of efficacy and lack of titration, as well as clinical development

D\*\*

Defendants admit allegations highlighted in blue but otherwise deny the allegations in this paragraph.

D\*\*

for new indications such as poststroke pain, cancer pain, restless leg syndrome and postoperative pain.” Ex. B at No. 39. This statement was false and misleading. In fact, Lyrica was not approved for these uses. Additionally, Lyrica has very serious adverse side effects, including dizziness, somnolence, visual disturbances, ataxia (problems walking), mood changes, weight gain, depression and suicidality. By failing to tell investors that Lyrica was being promoted by off-label marketing, while simultaneously implying that Lyrica was “successful” and its sales were growing, defendants deliberately misled investors as to Lyrica’s performance and future potential.

92. Defendants’ statements regarding Zyvox’s sales growth during the Class Period on 4/19/06 and 10/21/08, including that **“we saw good results from our in-line medicines and increasing contributions from new products”** and that **“[w]e continued to deliver steady results this quarter, with many of our most important medicines performing well around the world, including Lyrica, . . . Zyvox and Geodon,”** were also false and misleading when made. Ex. B at Nos. 12, 40. Defendants’ Zyvox statements were false because defendants unlawfully stated Zyvox was superior to vancomycin even though the FDA ordered Pfizer to cease that comparison in 2005. D\*

93. In 2005, the Company reported just \$589 million, \$291 million and \$618 million from Geodon, Lyrica and Zyvox sales, respectively. Defendants’ unlawful off-label marketing practices drove Geodon, Lyrica and Zyvox revenue growth during the Class Period such that by 2008, each of these drugs was considered a “blockbuster” drug generating over \$1 billion in annual sales. Lyrica alone accounted for over \$2.5 billion in sales. Defendants emphasized that Pfizer was experiencing significant revenue growth associated with these drugs, concealing that much of that growth was due to the Company’s pervasive off-label unlawful marketing practices. D\*

94. Defendants’ statements regarding the sales performance of Geodon, Zyvox and Lyrica and their impact on Pfizer’s bottom line were also false and misleading because defendants D

<sup>617336\_2</sup> D\* = Defendants admitted certain facts in connection with this paragraph in their Amended Answer, and those admissions are incorporated by reference here.

failed to disclose that the Company was off-label marketing these drugs in violation of Pfizer's 2004 CIA and Blue Book for the reasons set forth in ¶¶58-77, incorporated by reference herein.

### THE TRUTH IS REVEALED

95. Before the market opened on 1/26/09, the Company issued a release reporting that Pfizer had experienced 4Q08 revenue and EPS *declines* of 90%. The release stated: D\*

*Fourth-quarter 2008 results were impacted by a \$2.3 billion pre-tax and after-tax charge resulting from an agreement in principle with the Office of Michael Sullivan, the United States Attorney for the District of Massachusetts, to resolve previously disclosed investigations regarding allegations of past off-label promotional practices concerning Bextra, as well as other open investigations.*

96. In an effort to manipulate the adverse reaction of Pfizer shareholders by mitigating the impact of the drastic revelations concerning defendants' off-label abuses and their impact on Pfizer, including the \$2.3 billion in criminal and civil fines and the dramatic adverse impact the fines had on Pfizer's available cash (which caused Pfizer to reduce its dividend for the first time in 41 years), defendants and their counsel arranged to contemporaneously announce Pfizer's highly publicized acquisition of Wyeth. D

97. That same morning, 1/26/09, during the Company's conference call, defendants reiterated that: D\*

[D'Amelio:] *These significant year-over-year decreases were primarily driven by a \$2.3 billion pretax and after-tax charge* resulting from an agreement in principle to resolve previously disclosed investigations regarding allegations of past off-label promotional practices concerning Bextra, as well as other open investigations.

98. As a result of the disclosures that Pfizer's unlawful marketing practices and the impact thereof, including the payment of a \$2.3 billion fine and reduction of Pfizer's dividend, the price of Pfizer common stock declined from a closing price of \$17.45 on 1/23/09, the previous trading day, to close at \$15.65 on 1/26/09, a drop of more than 10% on volume of 210 million shares (more than five times the average daily trading volume of Pfizer's stock) as the artificial inflation D

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caused by defendants' fraud came out of Pfizer's stock price. A decline that was moderated by Pfizer's concurrent announcement of the \$68 billion acquisition of Wyeth.

### POST-CLASS PERIOD REVELATIONS

99. In the wake of Pfizer's announcement that it would pay \$2.3 billion in criminal fines and civil penalties related to the DOJ's investigation into the Company's off-label marketing practices, various news stories corroborated that defendants engaged in a fraudulent scheme to artificially prop up Pfizer's financial condition and conceal the material risk to the Company of defendants' illegal conduct.

100. On 9/2/09, the DOJ issued a release entitled "Justice Department Announces Largest Health Care Fraud Settlement in Its History; Pfizer to Pay \$2.3 Billion for Fraudulent Marketing," which provided further details of defendants' off-label practices. The release stated:

*American pharmaceutical giant Pfizer Inc. and its subsidiary Pharmacia & Upjohn Company Inc. (hereinafter together "Pfizer") have agreed to pay \$2.3 billion, the largest health care fraud settlement in the history of the Department of Justice, to resolve criminal and civil liability arising from the illegal promotion of certain pharmaceutical products, the Justice Department announced today.*

Pharmacia & Upjohn Company has agreed to plead guilty to a felony violation of the Food, Drug and Cosmetic Act for misbranding Bextra with the intent to defraud or mislead. . . . *Pfizer promoted the sale of Bextra for several uses and dosages that the FDA specifically declined to approve due to safety concerns.* The company will pay a criminal fine of \$1.195 billion, *the largest criminal fine ever imposed in the United States for any matter.* Pharmacia & Upjohn will also forfeit \$105 million, for a total criminal resolution of \$1.3 billion.

In addition, Pfizer has agreed to *pay \$1 billion* to resolve allegations under the civil False Claims Act that *the company illegally promoted four drugs – Bextra; Geodon, an anti-psychotic drug; Zyvox, an antibiotic; and Lyrica, an anti-epileptic drug – and caused false claims to be submitted to government health care programs for uses that were not medically accepted indications and therefore not covered by those programs.* The civil settlement also resolves allegations that Pfizer paid kickbacks to health care providers to induce them to prescribe these, as well as other, drugs. The federal share of the civil settlement is \$668,514,830 and the state Medicaid share of the civil settlement is \$331,485,170. *This is the largest civil fraud settlement in history against a pharmaceutical company.*

\* \* \*

“Illegal conduct and fraud by pharmaceutical companies puts the public health at risk, corrupts medical decisions by health care providers, and costs the government billions of dollars,” said Tony West, Assistant Attorney General for the Civil Division. “This civil settlement and plea agreement by Pfizer represent yet another example of what penalties will be faced when a pharmaceutical company puts profits ahead of patient welfare.”

***“The size and seriousness of this resolution, including the huge criminal fine of \$1.3 billion, reflect the seriousness and scope of Pfizer’s crimes,”*** said Mike Loucks, acting U.S. Attorney for the District of Massachusetts. ***“Pfizer violated the law over an extensive time period.*** Furthermore, at the very same time Pfizer was in our office negotiating and resolving the allegations of criminal conduct by its then newly acquired subsidiary, Warner-Lambert, Pfizer was itself in its other operations violating those very same laws. Today’s enormous fine demonstrates that ***such blatant and continued disregard of the law will not be tolerated.***”

101. On 9/14/09 the *National Law Journal* reported that “Prosecutors said ***recidivism was a key reason they were able to force a settlement that put the company on the hook for \$2.3 billion*** in fines and an admission of criminal conduct by its employees. Regulators and prosecutors paint a picture of a company where – from top to bottom – controls failed over marketing drugs like Bextra, the painkiller at the center of the latest settlement.”

D\*

102. On 9/23/09 the *New Haven Register* published an article, “Drug Companies Put Profits First,” in which it described the motive of defendants to conduct such a massive fraud:

D\*

***Pfizer paid off doctors to prescribe unapproved uses of its drugs.***

\* \* \*

Pfizer had promoted four of its drugs to doctors for uses not approved by the U.S. Food and Drug Administration because of the potential threat to patient health. ***Promoting these off-label uses helped drive Pfizer’s profits higher. They also resulted in millions of dollars in false claims for Medicare and Medicaid coverage that the settlement helps recoup.***

\* \* \*

***Pfizer’s behavior was particularly blatant. It had been caught before and promised never to do it again – a legal pledge it had no qualms in breaking. This was the fourth time since 2002 that it has settled charges of illegal marketing.***

103. On 10/21/09, the Honorable Douglas P. Woodlock of the United States District Court for the District of Massachusetts oversaw the criminal sentencing of Pharmacia, at which he made the following observation:

D\*

[S]uffusing the materials that *I have been provided with is a lengthy pattern by persons, who may or may not still be with the corporation in its new incarnation, that are instinct with violations for which the corporation is pleading guilty.* It seems to me that those are things, even if they are not winners from the government's point of view, which bear prosecution.

It has, I think, become something of cost of doing business, a very high cost of doing business, for some of these corporations to shed their skin like certain animals and leave the skin behind and move on to the future without ultimately giving the public what it is entitled to, which is the satisfaction of knowing that there has been full evaluation of the criminal responsibility of the individuals who occupied that skin.

104. On 11/9/09, *Bloomberg* published an article entitled "Pfizer Broke the Law by Promoting Drugs for Unapproved Uses," which reported:

D\*

*"Marketing departments of many drug companies don't respect any boundaries of professionalism or the law,"* says Jerry Avorn, a professor at Harvard Medical School in Boston and author of "Powerful Medicines: The Benefits, Risks, and Costs of Prescription Drugs" (Random House, 2004). *"The Pfizer and Lilly cases involved the illegal promotion of drugs that have been shown to cause substantial harm and death to patients."*

\* \* \*

*If the law is clear, why do drug companies keep breaking it? The answer lies in economics. Pharmaceutical companies spend about \$1 billion to develop and test a new drug. To recoup their investment, the companies want doctors to prescribe their drugs as widely as possible.*

\* \* \*

*In the January 2004 settlement negotiations with Loucks, Sullivan and two other prosecutors, Pfizer's lawyers assured the U.S. Attorney's Office that the company wouldn't market drugs off-label.*

\* \* \*

*"They asserted that the company understood the rules and had taken steps to assure corporate compliance with the law," Loucks says. "We remember those promises."*

D\* = Defendants admitted certain facts in connection with this paragraph in their Amended Answer, and those admissions are incorporated by reference here.

*What Pfizer's lawyers didn't tell the prosecutors was that Pfizer was at that moment running an off-label marketing promotion using more than 100 of its salespeople.* They were pitching Bextra, a Pfizer sales manager admitted when she pleaded guilty to misbranding a drug on March 30, 2009.

*Jeff Kindler, who became Pfizer's general counsel in 2002, supervised the lawyers who made the promises to prosecutors.* By 2004, Kindler increased the compliance budget 12-fold. He became chief executive officer in 2006. In Pfizer's ethics guide, he says stories about misbehaving companies and executives abound.

*"Pfizer truly stands apart," he says. "I am proud of our record."* On Oct. 1, Kindler was elected to the board of the Federal Reserve Bank of New York. Kindler declined to comment.

\* \* \*

In the same time period that Pfizer was marketing Bextra off-label, the Company's sales force was *promoting another drug, Zyvox, improperly, Pfizer admitted at the time of its September plea agreement.*

*Zyvox* was approved in 2000 by the FDA for treating MRSA-caused pneumonia and skin infections. Raniero told federal prosecutors that Pfizer began the Zyvox campaign in 2001. *The company admitted to falsely claiming that the drug was better than other medications for treating MRSA pneumonia.*

"Misleading Promotion"

*On July 20, 2005, the FDA sent a letter to Hank McKinnell, then Pfizer's CEO, saying, "Your misleading promotion of Zyvox, and in particular your unsubstantiated implied claims regarding its superiority to vancomycin, poses serious health and safety concerns."*

\* \* \*

*By 2007, the criminal and civil cases against Pfizer, its employees and its subsidiaries had started to mount. The tally of drugs cited by federal prosecutors for off-label promotion reached six by 2009.* In April 2007, P&U pleaded guilty to a felony charge of offering a \$12 million kickback to a pharmacy benefit manager.

\* \* \*

"Upsetting to Me"

*U.S. District Court Judge Patti Saris, who had presided over the Neurontin whistle-blower case before the Pfizer probe,* accepted Schering's plea in her Boston courtroom in January 2007. She *expressed dismay with the drug industry.*

***“It’s been upsetting to me how many of the big pharmaceutical companies have engaged in what I view as clearly illegal behavior in terms of off-label marketing,” she said. “It almost seems as if the pharmaceutical companies said ‘Yeah, yeah, yeah’ to the FDA and then went and did it anyway.”***

105. The media continued to report on Pfizer’s massive fines and guilty plea for more than a year after it was first announced. For example, on 2/23/10 in a *Business Ethics*’ article, Pfizer’s then-Chief Compliance Officer, Douglas Lankler, was quoted in a *Business Ethics*’ article, acknowledging that Pfizer’s plea of guilty and \$2.3 billion fine was ““like being hit in the face by a two-by-four. Even for a big company, it’s a very, very difficult thing to go through.”” Lankler also admitted in an 4/2/10 *CNN.com* article that ““unequivocally . . . Pfizer perceived the Bextra matter as an incredibly serious one.””

D\*

106. On 2/3/10, *Bloomberg* reported: “Profit in the period more than doubled” as compared to ***the fourth quarter in 2008***, “when ***results were hurt by a \$2.3 billion legal settlement*** related to the marketing of the Bextra painkiller.” Likewise, *Dow Jones* reported on the same day that Pfizer’s 4Q09 earnings “more than doubled from a ***year-earlier profit that was dampened***” by a ***legal settlement***.

D\*

107. On 3/1/10, *Life Extension Magazine* published an editorial, “As We See It: Drug Company Pleads Guilty to Health Fraud,” castigating Pfizer for its scheme to illegally promote its drugs:

D\*

***It’s one thing to break the law by paying doctors to prescribe drugs that at least have some degree of documented efficacy, but Pfizer went further than this.***

The government’s complaint describes how ***Pfizer created new uses for its patented drugs and then engaged in all kinds of devious schemes to illegally promote these “new uses” to physicians.*** For instance, ***Pfizer claimed their drug Lyrica was superior to lower-cost generic medications to treat neuropathic and surgical pain, and then illegally compensated doctors to prescribe Lyrica for these indications.***

*Geodon* is a drug approved to treat schizophrenia or acute bipolar mania, but the government outlined in its complaint that *Pfizer was inappropriately and illegally promoting it for use in children and adults to treat autism, attention deficit hyperactivity disorder, mood disorders, and depression.*

108. More recently, on 10/3/10, the *New York Times* published an article, “Side Effects May Include Lawsuits,” which examined the role that marketing played in making antipsychotic drugs, including *Pfizer’s Geodon*, the top-selling class of pharmaceuticals in America. *Pharmaceutical companies “sold the story [that the antipsychotics are] more safe, when they aren’t” . . . . “They had to cover up the problems. Right from the start, we got this false story.”*

D\*

The article continued:

*“It’s the money,” says Dr. Jerome L. Avorn, a Harvard medical professor and researcher. “When you’re selling \$1 billion a year or more of a drug, it’s very tempting for a company to just ignore the traffic ticket and keep speeding.”*

\* \* \*

*[The pharmaceutical companies] were aware that they were using questionable tactics when they marketed these powerful, expensive drugs.*

*Such marketing, according to analysts and court documents, included, payments, gifts, meals and trips for doctors, biased studies, ghostwritten medical journal articles, promotional conference appearances, and payments for postgraduate medical education that encourages a pro-drug outlook among doctors. All of these are tools that federal investigators say companies have used to exaggerate benefits, play down risks and promote off-label uses . . . .*

\* \* \*

[According to Dr. Stefan Kruszewski, a psychiatrist who once worked as a paid speaker for Pfizer,] *“it got to the point where I was . . . given slides and told, ‘We’ll give you a thousand dollars if you say this for a half-hour.’” . . .*

*. . . “They made it all up[.]” . . . “It was never true.”*



## ADDITIONAL ALLEGATIONS OF SCIENTER

### Pfizer's Corporate Integrity Agreements Evidence Scienter

109. Pfizer's repeated disregard for the law underscores defendants' scienter. In the three-and-a-half years leading up to the Class Period, Pfizer had entered into not just one, but *two* different CIAs, each which required Pfizer to comply with the law and abide by specific codes of conduct. D\*

110. In 10/02, Pfizer and its subsidiaries, Warner-Lambert and Parke-Davis, agreed to pay a \$49 million settlement and entered into a CIA with the OIG related to its Medicaid Rebate payments for the drug Lipitor. The 2002 CIA required Pfizer to maintain internal procedures designed to ensure compliance with rules against paying kickbacks to physicians in violation of the Medicaid program. D\*

111. In 2004, Pfizer entered into yet another CIA when it agreed to settle the Neurontin investigation for \$430 million. The 2004 CIA was negotiated by defendant Kindler and specifically addressed the rampant off-label marketing of Neurontin by requiring policies and procedures at Pfizer to prevent further off-label marketing. The policies and procedures required that Pfizer put "in place strong review and disciplinary measures to ensure that its activities: (i) are in compliance with all Federal health care program requirements and FDA requirements, and (ii) meet Pfizer's goal of ensuring high ethical standards in all aspects of its business practice." D\*

112. Pfizer, not its subsidiary Warner-Lambert, was responsible for complying with the 2004 CIA. *The 2004 CIA required that Pfizer itself notify the FDA and the OIG of any written reports, correspondences or communications in connection with Pfizer's or a covered Pfizer employee's promotion, discussion or dissemination of information concerning off-label uses of Pfizer's products.* D\*

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113. The agreement is clear that off-label marketing was prohibited and that the members of Pfizer's senior management were responsible for monitoring the Company's marketing program to ensure that Pfizer was not a repeat offender. *See* ¶¶41-45; Ex. B. The 2004 CIA also required Pfizer to promote and adhere to a number of codes of conduct, including: D\*

- *full compliance with all federal healthcare program requirements and FDA requirements, including marketing, selling and promoting its products in compliance with all government contracting requirements;*
- all employees covered under the CIA shall comply with all federal healthcare program requirements and FDA requirements; and
- *all employees covered under the CIA were expected to report suspected violations of any federal healthcare program requirements or FDA requirements.*

114. To comply with the codes of conduct established in the CIA, Pfizer was required to develop policies and procedures that addressed, among other things, the following: D\*

- *“methods for selling, marketing and promoting Pfizer products in compliance with all applicable Federal health care program requirements, including, but not limited to, the Federal anti-kickback statute”;*
- *“methods for selling, marketing, promoting, advertising, and disseminating information about off-label uses of Pfizer's products in compliance with all applicable FDA requirements”;*
- *“the manner in which [Pfizer's] Medical Information Department receive[d] and respond[ed] to requests for information about off-label uses; the form and content of information disseminated by the Medical Information Department in response to such requests, and the internal review process for the information dissemination”;* and
- “speaker meetings, advisory board meetings, and all other consultant arrangements . . . designed to ensure that the consultant arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program requirements and with FDA requirements relating to the dissemination of information about off-label uses of products.”

115. The 2004 CIA required all officers in Pfizer's U.S. pharmaceutical operations to certify that they received, read, understood and would abide by Pfizer's Code of Conduct, which included complying with all federal healthcare program requirements and FDA rules. As Pfizer's D\*

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General Counsel, defendant Kindler, and later defendant Waxman, were responsible for Company-wide compliance and everyone covered by the CIA were responsible for reporting to them. Because defendants were required to monitor compliance with laws precluding off-label marketing, they were informed of or were reckless in knowingly ignoring the Company-wide off-label promotion of Bextra, Geodon, Lyrica and Zyvox.

### **The Scope and Content of the Criminal Plea Agreement Adds to Scienter**

116. In August 2009, Pfizer created a subsidiary, Pharmacia & Upjohn, for the purpose of insulating Pfizer from criminal charges, as a criminal guilty conviction related to off-label marketing drugs would prevent Pfizer from participating in the Medicare program, a death knell for a pharmaceutical company. Defendants caused Pharmacia & Upjohn to accept the guilty plea. Thus, Pharmacia & Upjohn pled guilty and was excluded from Medicare *without having ever sold a single drug*. Pharmacia & Upjohn entered into a plea agreement with the United States Attorney for the District of Massachusetts as a result of Pfizer's off-label marketing of Bextra between 2/02 and 4/05; Pfizer paid a \$1.195 billion criminal fine, and a \$105 million criminal forfeiture. *"Pharmacia expressly and unequivocally admits that it knowingly, intentionally and willfully committed the crime charged in the attached Information and is in fact guilty of the offense*, and agrees that it will not make any statements inconsistent with this explicit admission." The facts in the Information mentioned in the plea agreement, included, but are not limited to:

- *"PHARMACIA's headquarters marketing team created marketing messages and materials for the PHARMACIA sales force that promoted Bextra for unapproved uses and dosages, including materials that directed PHARMACIA's sales force to aggressively pursue written surgical and pain management standing orders for Bextra, including for uses for which Bextra was unapproved";*
- *"PHARMACIA managers instructed their sales teams to promote Bextra for the acute pain of surgery, both pre- and post-operatively, even though they knew that Bextra was not FDA-approved for these uses, and without disclosing to physicians, customers and others that the FDA specifically declined to approve Bextra for those*

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uses and doses, and that the FDA's refusal was due in part to a safety concern about potential serious adverse events, including cardiovascular events, in some surgeries based upon the results of the CABG I study";

- ***"PHARMACIA managers trained and directed their sales teams to seek written surgical and pain management protocols, standing orders and pathways from physicians, hospitals, and other customers for use in pre-and post-operative surgical situations";***
- ***"PHARMACIA's sales representatives also created sham physician requests for medical information about unapproved uses in order to send unsolicited information to physicians about unapproved uses and dosages of Bextra";*** and
- ***"PHARMACIA also promoted Bextra for unapproved uses and dosages through a 'publication strategy' whereby PHARMACIA initiated, funded, sponsored and sometimes drafted or hired medical write vendors to draft articles about Bextra for unapproved uses and dosages in order to promote these uses and dosages, without always appropriately disclosing PHARMACIA's role in the process."***

117. The Information thus confirms that the off-label marketing of Bextra was not only deliberate but was premeditated by senior management. D

118. The Blue Book also assured investors that it had a "well-structured compliance system" consisting principally of the "Corporate Compliance Officer, the Corporate Compliance Committee Officer, the Corporate compliance Group, and local Compliance Liaisons." The Corporate Compliance Officer was Pfizer's General Counsel (defendant Kindler and then defendant Waxman), and was "responsible for overseeing Pfizer's compliance system, including the internal auditing, monitoring, and self-evaluation programs relating to the legal and regulatory obligations of the Company." Further, "[t]he Corporate Compliance Officer ensures that there is broad application and consistent interpretation of our standards throughout the Company." He reported directly to, among others, the CEO (defendant McKinnell and then defendant Kindler). Additionally, the Corporate Compliance Committee contained representatives from each business division of Pfizer, included defendants D'Amelio and Read, and was responsible for overseeing "Pfizer's compliance strategy and system, and . . . charged with keeping the Corporate Compliance Officer, the Board of D\*

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Directors and senior management informed of significant compliance issues, risks, and trends.” The “Corporate Compliance Group works with the Corporate Compliance Officer to ensure adherence to laws, regulations, and Company policies on a day-to-day basis.”

119. Additionally, Pfizer’s Compliance Liaisons, according to a 2005 PowerPoint presentation of a Pfizer assistant General Counsel, were charged with ensuring not only that the Corporate Compliance Officer, but also that the CEO and CFO were “up-to-date on compliance issues at every Pfizer location.”

D\*\*

120. Consistent with the CIA and Pfizer’s stated policies, the Blue Book indicates that all “significant violations of applicable law or Company policy . . . must be reported to the Corporate Compliance Group for investigation.” Factors that weigh in favor of “significance” include (i) whether the action was intentional or part of a pattern; (ii) management involvement; (iii) exposure to the public of health or safety risks; and (iv) the consequences to the Company.

D\*

#### **Defendants’ Treatment of the Blue Book as a Sham Bolsters Scienter**

121. Many of the *qui tam* relators, percipient witnesses to defendants’ fraud, reported unlawful off-label marketing up the ladder as required by the Blue Book and the 2004 CIA. Unfortunately, those at the top of the ladder, senior management at Pfizer, were willing to ignore the 2004 CIA and continued to promote off-label sales. The *qui tam* relators’ accounts of widespread off-label marketing at Pfizer’s highest levels contemporaneous with and after execution of the 2004 CIA include:

D\*

- In 9/04, relator DeMott *questioned* Pam Robertson (“Robertson”), Assistant to the Alta Division Regional Director, about *promoting Bextra in contradiction of the 2004 CIA*. Robertson’s response was that the promotion *instructions came directly from Pfizer Executive Vice President Rick Birch*;
- In 2003 and 2004, DeMott repeatedly reported to his District Manager Michael Krams and to *Pfizer’s national compliance officers in New York* that Pfizer’s claims about Bextra were false;

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D\*\* = As indicated in their Amended Answer, Defendants respectfully, refer the Court to the cited document[s] for its/their complete content.

- **On 3/29/04, DeMott e-mailed Human Resource Manager Andrew Powell** a message regarding the off-label use of Geodon at the Townstreet Clinic in Columbus, Ohio. Because of continued marketing, illegal payments and formulary promoting Pfizer drugs at the clinic, the high rate of Geodon use continued;
- During the **Lyrica pre-launch meeting** in August 2005, relator Schildauer raised concerns about using unsubstantiated comparative panels to promote Lyrica. His superior, District Manager Tracy Lucas, responded that representatives were to promote that Lyrica was a “better agent” than gabapentin despite the lack of any head-to-head adequate and well-controlled clinical trials;
- **On 5/12/06, relator Liter anonymously voiced his concerns about using medical inquiries to market Lyrica with Pfizer’s corporate compliance department.** During the first week of 6/06, Lisa Shrayner (“Shrayer”), Pfizer Corporate Counsel, contacted Liter and scheduled a meeting for 6/12/06 to further discuss his concerns regarding the promotion of Lyrica. **On 6/12/06, Liter met with Shrayer and attorneys from the law firm Pfizer retained as outside counsel. During this meeting Liter provided these individuals copies of the Lyrica Launch Tracker, e-mails with Medical Information letters and unapproved FDA indications for Lyrica;** and
- According to relator Westlock, after receiving a flyer for a Pfizer funded Geodon promotional presentation at NAMI **in 1/07** regarding children’s psychotic needs, he **called and e-mailed Pfizer Corporate Compliance.**

122. The account of Holloway, a former Pfizer regional sales manager, similarly confirms defendants’ scienter. Holloway admitted that her region promoted the use of protocols for off-label usage, including to attain orthopedic, podiatry, urology, ob/gyn, ENT and dental indications. According to Holloway, “[c]orporate tracked this information, and at no time did it inform Ms. Holloway that any of the reported protocols were inappropriate. Instead, **the instruction was to get more protocols.**”

123. Consistent with Holloway’s account, on a 1/19/06 conference call defendant McKinnell acknowledged that he kept close tabs on the market share of Pfizer’s drugs and the performance of the sales force: “I watch those numbers very closely. At 7:30 Monday morning I am looking at my computer screen” – sales which were fueled by off-label marketing.

## **Defendants' Compensation and Insider Trading in Excess of \$150 Million Support Scienter**

124. Pfizer's executive compensation plan provided substantial financial incentive for each of the Individual Defendants to engage in the misconduct at issue here. During the Class Period, according to Pfizer's 2007, 2008 and 2009 proxies filed with the SEC, Pfizer's executive compensation was tied directly to the performance of the Company, which defendants' misconduct was designed and did artificially inflate. Additionally, defendants encouraged the off-label promotion of Pfizer's drugs by compensating Pfizer's sales force for sales derived from their unlawful practices. For example, certain defendants have admitted that until at least December 2007 Pfizer commissioned sales representatives for Geodon prescriptions written by pediatricians and pediatric institutions despite the fact Geodon was not approved for children.

D\*

125. Pfizer's executive compensation was based on the Company's financial performance and the individual executive's performance related to the Company's strategic objectives. For example, each of the defendants had between 20%-50% of his or her FY06 incentive compensation tied to Pfizer's reported revenue, EPS and/or cash flow, each of which was artificially inflated by defendants' unlawful off-label marketing practices. For 2007, the annual incentive pay was adjusted to place more of an emphasis on the Company's financial performance, accounting for 45%-70% of defendants' annual incentive pay. For 2008, 50% of defendants' annual incentive pay was based on aspects of Pfizer's financial performance inflated by defendants' scheme.

D\*

126. Pfizer executives also received long-term incentive pay during the Class Period. As part of the long term incentive pay, Pfizer granted stock options, restricted stock units and performance-based shares. In 2008, 25% of the long-term incentive equity awards was transferred to short-term equity awards.

D\*



127. Under Pfizer's compensation program, defendants<sup>12</sup> received over \$50 million in compensation during the Class Period as follows: D\*

Name	Year	Salary	Bonus	Stock Awards	Non-Equity Incentive Plan Compensation	Change in Pension Value & Non-Qualified Deferred Compensation Earnings	All Other Compensation	Total
Shedlarz	2007	\$1,056,875	\$ 951,200	\$ 62,339	\$ 0	\$13,104,860	\$ 188,766	\$17,159,904
	2006	\$1,008,225	\$1,263,400	\$3,181,563	\$ 0	\$ 1,381,064	\$ 185,843	\$10,275,470
Levin	2007	\$ 687,943	\$ 486,750	\$ 36,998	\$ 0	\$ -154,923	\$2,104,635	\$ 5,004,265
	2006	\$ 784,575	\$ 580,600	\$2,026,454	\$ 0	\$ 212,143	\$ 70,345	\$ 4,766,299
Kindler	2008	\$1,575,000	--	\$4,715,947	\$3,000,000	\$ 759,298	\$ 438,261	\$13,770,422
	2007	\$1,462,500	\$3,100,000	\$1,162,835	--	\$ 477,783	\$ 441,456	\$ 9,513,440
	2006	\$1,103,883	\$3,300,000	\$2,736,265	--	\$ 422,091	\$ 265,318	\$ 9,799,234
D'Amelio	2008	\$1,051,500	--	\$4,328,129	\$1,250,000	\$ 423,085	\$ 127,303	\$ 8,132,350
	2007	\$ 320,625	\$4,040,000	\$ 907,717	--	\$ 927,990	\$ 32,278	\$ 6,434,532
Read	2008	\$1,051,500	--	\$1,732,560	\$1,250,000	\$ 963,274	\$ 237,188	\$ 6,835,125
	2007	\$ 944,083	\$ 990,000	\$ 190,134	--	\$ 133,784	\$ 160,626	\$ 4,053,307
	2006	\$ 813,450	\$ 667,200	\$1,651,580	--	\$ 455,792	\$ 86,159	\$ 4,779,162
McKinnell	2006	\$2,270,500	--	\$8,315,642	--	--	\$ 383,517	\$19,418,446
Katen	2006	\$1,220,300	\$1,383,000	\$4,616,454	--	\$17,426,208	\$ 287,311	\$28,995,078

128. The Individual Defendants also traded their Pfizer stock while in possession of adverse material information regarding Pfizer including: (i) Pfizer's unlawful off-label marketing; and (ii) its false financial statements. The proceeds from defendants illicit trades exceeded \$22 million and included: Levin received \$5 million; Read received \$2.3 million; McKinnell received \$6.4 million; Shedlarz received \$2.1 million; Feczko received \$3 million; and Katen received \$4 million. Attached hereto as Ex. C are the dates and amounts of each of these defendants' trades. D

### NO SAFE HARBOR

129. The statutory safe harbor provided for forward-looking statements ("FLS") under certain circumstances does not apply to any of the allegedly false statements pleaded in this D

<sup>12</sup> Defendants Waxman's, Feczko's and Kelly's compensations are not publicly available in Pfizer's proxies.

<sup>617336\_2</sup> D\* = Defendants admitted certain facts in connection with this paragraph in their Amended Answer, and those admissions are incorporated by reference here.



complaint. Many of the specific statements pleaded herein were not forward-looking and were not identified as FLS when made.

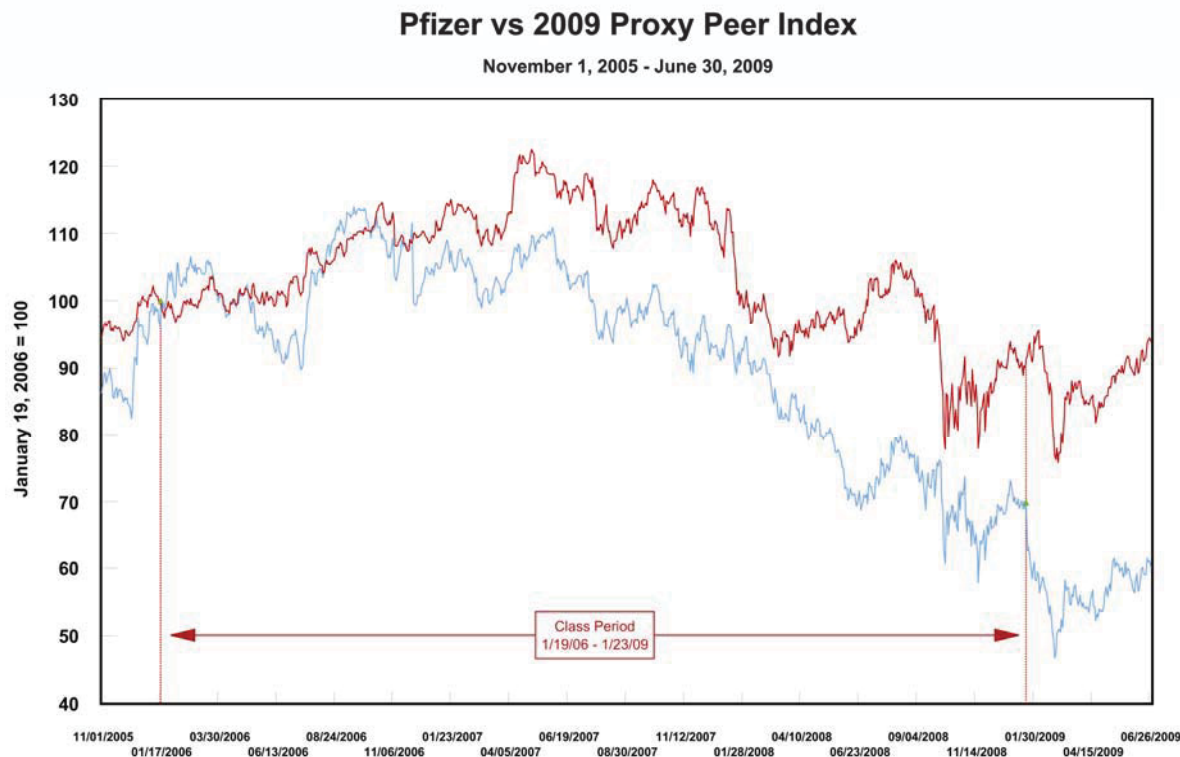
130. To the extent there were any FLS, there were no *meaningful* cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly FLS. Rather, defendants statements were boilerplate warnings. Further, Pfizer's verbal "Safe Harbor" warnings accompanying its oral FLS issued during the Class Period were ineffective to shield those statements from liability.

131. The defendants are also liable for any false or misleading FLS pleaded because, at the time each FLS was made, the speaker knew the FLS was false or misleading and the FLS was authorized and/or approved by an executive officer of Pfizer who knew that the FLS was false. None of the historic or present tense statements made by defendants were assumptions underlying or relating to any plan, projection or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections made by defendants expressly related to or stated to be dependent on those historic or present tense statements when made.

#### **PROXIMATE LOSS CAUSATION/ECONOMIC LOSS**

132. As detailed herein, defendants engaged in a scheme and wrongful course of business, which was designed to and did deceive Class Period purchasers of Pfizer's securities as defendants misrepresented and/or omitted material information about Pfizer's drug sales, off-label marketing practices and financial performance. When the materialization of the risks that had been fraudulently concealed by defendants occurred and the true facts became known to the market and investors, Pfizer's stock price fell precipitously as the prior artificial inflation came out of the price, causing loss and damages to plaintiffs and members of the Class.

133. Defendants' false statements and omissions, identified herein at ¶¶ 58-74, 76, 78, 81-82, 84-92, had the intended effect and caused Pfizer stock to trade at artificially inflated levels during the Class Period as reflected in the chart below:<sup>13</sup>



134. As a direct result of the 1/26/09 disclosure that Pfizer agreed to pay \$2.3 billion to settle criminal and civil violations arising out of defendants' off-label marketing practices and corresponding dividend cut, Pfizer's stock price dropped immediately on the NYSE, falling from a closing price of \$17.45 on 1/23/09, the previous trading day, to close at \$15.65 on 1/26/09, a decline of more than 10.3%. By contrast, the peer group index increased during the same period. Trading volume increased tremendously to over 210 million shares on 1/26/09 or more than 500% the normal daily volume. Thus, in a single day over \$12 billion in Pfizer's market capitalization was eliminated

<sup>13</sup> The peer group index is derived from the pharmaceutical peer group listed in Pfizer's 2009 proxy.

and investors suffered economic losses. This drop removed the artificial inflation from Pfizer's stock price, causing real economic loss to investors who purchased Pfizer securities during the Class Period.

135. The decline in Pfizer's stock price at the end of the Class Period was a direct result of the materialization of the risks concealed by defendants' prior false statements and omissions and the nature and extent of the truth revealed to investors and the market. The adverse consequences of the end of the Class Period disclosures, including the largest criminal fine in U.S. history and Pfizer's first dividend cut in four decades, were foreseeable to defendants at all relevant times. Indeed, as set forth above, the defendants knew of the adverse consequences to Pfizer's stock price, reputation, and cash flow (in the form of fines) as well as the impact on Pfizer's dividend, prior to the 1/26/09 disclosure. Defendants' conduct proximately caused foreseeable losses and damages to plaintiffs and members of the putative Class. The timing and magnitude of Pfizer's stock price declines negate any inference that the loss suffered by plaintiffs and other Class members was caused by changed market conditions, macroeconomic or industry factors or Company-specific facts unrelated to defendants' fraudulent conduct. As noted above, on 1/26/09, the same day Pfizer's stock price fell nearly \$2.00 per share due to the revelation of defendants' fraud, Pfizer's peer group index increased.

136. Defendants tried to offset the dramatic adverse announcement of the largest healthcare related fine in U.S. history by concurrently announcing on 1/26/09 that Pfizer had agreed to acquire Wyeth. But the *Wall Street Journal* had already leaked the merger on the preceding Friday morning, 1/23/09, resulting in more than double the trading volume of Pfizer's shares and driving Pfizer's stock price up from a close of \$17.21 on 1/22/09 to \$17.45 on 1/23/09. Other media outlets, such as Fox Business Network LLC's, "Money for Breakfast" 7:00 a.m. EST show on

1/23/09 broadcasted that the *Financial Times* reported “that the deal could be announced as soon as Monday [1/26/09].”

137. The merger transformed Pfizer overnight into a highly diversified pharmaceutical and healthcare company and insured Pfizer’s place as the largest pharmaceutical company in the world. Defendant Kindler described the deal on a 1/26/09 conference call as “transformational and positions [Pfizer] to be in the best possible position for future success.”

D\*

138. Despite defendants’ maneuver to announce the \$68 billion Wyeth acquisition on 1/26/09, Pfizer’s stock price still declined more than 10% that day, in reaction to the revelation of defendants’ illegal off-label marketing tactics and the resulting fine and dividend reduction. The news of the Wyeth merger had already been absorbed by the market on 1/23/09. The economic loss, *i.e.*, damages, suffered by plaintiffs and other members of the Class, was a direct result of defendants’ fraudulent scheme to illegally promote Pfizer’s drugs off-label and hide that conduct from investors. Defendants’ scheme artificially inflated Pfizer’s stock price and maintained the price at artificially inflated levels until the subsequent significant decline in the value of Pfizer’s stock occurred when the risks concealed by defendants’ prior misrepresentations and omissions materialized and were publicly revealed.

D

139. Thus, Pfizer attempted but failed to obscure the impact of its fraud by announcing the Wyeth merger on the same day it announced the \$2.3 billion in penalties and fines. Defendants rushed to close the Wyeth merger so they could dilute the adverse stock price impact they knew would result from disclosing that their unlawful off-label marketing scheme had existed for years and had now come to an end, forcing Pfizer to cut its dividend for the first time in 41 years. On 1/26/09 – the day of the twin announcements – *The AmLaw Daily* published an article detailing the timing of this maneuver stating:

D\*\*

<sup>617336\_2</sup> D\* = Defendants admitted certain facts in connection with this paragraph in their Amended Answer, and those admissions are incorporated by reference here.

D\*\* = As indicated in their Amended Answer, Defendants respectfully, refer the Court to the cited document[s] for its/their complete content.

Dennis Block, an M&A partner at Cadwalader, Wickersham & Taft, first got the call in June: his longtime client, Pfizer, was interested in buying rival Wyeth in what would likely be the largest deal in the history of the pharmaceutical industry. ***The deal sputtered off and on for more than six months until Thursday [1/22/09], when Block says Pfizer indicated it was ready to get the deal done – and fast.***

Block left his office for only a couple of hours a night over the next four days as he and Wyeth's attorneys at Simpson Thacher & Bartlett ***rushed to complete the \$68 billion takeover before the markets opened today.***

They succeeded, despite Wyeth's insistence that Pfizer agree to an unprecedented breakup fee of \$4.5 billion should it back out of the deal; that's twice as large as a typical breakup fee in a deal this big, the New York Times reports.

\* \* \*

***It's not all good news. Pfizer is set to fire 15,000 of the combined company's 130,000 employees and cut its dividend, in part because of a \$2.3 billion charge it is taking in anticipation of a settlement with government investigators over alleged off-label promotion of the painkiller Bextra. Cadwalader also advised Pfizer on that matter, Block says.***

140. The following day, the *Wall Street Journal*, the *New York Times* and the *Associated Press* issued articles corroborating that Pfizer's disclosure of its \$2.3 billion charge for off-label marketing was dramatically negative news for the market, and that the timing of the disclosure of the Wyeth merger was not a coincidence:

- *Wall Street Journal* (1/27/09) – “***The takeover announcement came amid the kind of bleak industry news that caused Pfizer Chief Executive Jeffrey Kindler to search for a big deal to begin with. The two companies said that their net income was down in the fourth quarter. And Pfizer reported taking a record \$2.3 billion charge to resolve a federal investigation into the off-label marketing of withdrawn painkiller Bextra.***”
- *New York Times* (1/27/09) – “After announcing the \$68 billion megamerger with Wyeth on Monday morning, ***Pfizer's chief executive, Jeffrey B. Kindler, did not have much time to celebrate. There was too much gloomy news to deal with.*** The companies' combined work force of 128,000 will shed 19,000 jobs. Pfizer will slash its stock dividend in half. And ***Pfizer is taking a \$2.3 billion charge to settle a federal investigation over illegal off-label promotion of its former painkiller, Bextra. . . . On any other day, the Bextra settlement might have been big news for Pfizer – which is why some analysts said the company had probably decided to disclose it on Monday.***”

- *Associated Press* (1/27/09) – “Pfizer Inc., the world’s largest drugmaker, said Monday it is buying rival Wyeth for \$68 billion in a deal that will quickly boost Pfizer’s revenue and diversification and, if it works as advertised help the company become more nimble. . . . It comes as ***Pfizer’s 2008 fourth-quarter profit takes a brutal hit from a \$2.3 billion legal settlement over allegations it marketed pain reliever Bextra and possibly other products for indications that had not been approved.***”

#### APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD-ON-THE-MARKET

141. Plaintiffs will rely upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things:

D

(a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

(b) The omissions and misrepresentations were material;

(c) The Company’s stock traded in an efficient market;

(d) The misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company’s stock; and

(e) Plaintiffs and other members of the Class purchased Pfizer securities between the time defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

142. At all relevant times, the market for Pfizer securities was efficient for the following reasons, among others:

(a) As a regulated issuer, Pfizer filed periodic public reports with the SEC;

(b) Pfizer trades on the NYSE; and

(c) Pfizer regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the major

D

news wire services and through other wide-ranging public disclosures, such as communications with the financial press, securities analysts and other similar reporting services.

### CLASS ACTION ALLEGATIONS

143. Plaintiffs bring this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased Pfizer securities during the Class Period (the “Class”). Excluded from the Class are defendants and their families, directors and officers of Pfizer and their families and affiliates.

D\*

144. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. Pfizer traded on the NYSE and had more than seven billion shares of stock outstanding, owned by thousands of persons. Members of the Class may be identified from records maintained by Pfizer or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

D\*

145. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual class members include:

D

- (a) Whether the 1934 Act was violated by defendants;
- (b) Whether defendants omitted and/or misrepresented material facts;
- (c) Whether defendants’ statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;
- (d) Whether defendants knew or recklessly disregarded that their statements were false and misleading;



(e) Whether the prices of Pfizer securities were artificially inflated; and

(f) The extent of damage sustained by class members and the appropriate measure of damages.

146. Plaintiffs' claims are typical of those of the Class because plaintiffs and the Class sustained damages from defendants' wrongful conduct in violation of federal law that is complained of herein. D

147. Plaintiffs will adequately protect the interests of the Class and have retained counsel who are experienced in class action securities litigation. Plaintiffs have no interests which conflict with those of the Class. D

148. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. D

## COUNT I

### For Violation of §10(b) of the 1934 Act and Rule 10b-5 Against All Defendants

149. Plaintiffs incorporate ¶¶1-148 by reference as if fully set forth herein. D\*

150. During the Class Period, defendants disseminated or approved the false statements specified above, which they knew or recklessly disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading. D

151. Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they:

(a) employed devices, schemes, and artifices to defraud; D

(b) made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

<sup>617336\_2</sup> D\* = Defendants admitted certain facts in connection with this paragraph in their Amended Answer, and those admissions are incorporated by reference here.

(c) engaged in acts, practices and a course of business that operated as a fraud or deceit upon plaintiffs and others similarly situated in connection with their purchases of Pfizer securities during the Class Period.

152. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the business, operations and future prospects of Pfizer as specified herein.

153. Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information, and engaged in acts, practices and a course of conduct as alleged herein in an effort to assure investors of Pfizer's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and omitting to state material facts necessary in order to make the statements made about Pfizer and its business operations and future prospects in the light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of Pfizer securities during the Class Period.

154. Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Defendants' material misrepresentations and/or omissions were done knowingly, deliberately or recklessly and for the purpose and effect of concealing Pfizer's true operating condition and future business prospects from the investing public and supporting the artificially inflated price of its publicly traded securities.

155. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of Pfizer securities were artificially inflated during the Class Period. In ignorance of the fact that market prices of Pfizer's publicly traded securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by defendants, or upon the integrity of the market in which the securities trade and/or on the absence of material adverse information that was known to or recklessly disregarded by defendants but not disclosed in public statements by defendants during the Class Period, plaintiffs and the other members of the Class acquired Pfizer's securities during the Class Period at artificially high prices and were damaged by the subsequent decline in stock price when the relevant truth concealed by defendants' fraud scheme was revealed to the market and the risks concealed by the fraud scheme began to materialize. D

156. Plaintiffs and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Pfizer securities. Plaintiffs and the Class would not have purchased Pfizer securities at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by defendants' misleading statements. D

157. As a direct and proximate result of these defendants' wrongful conduct, plaintiffs and the other members of the Class suffered damages in connection with their purchases of Pfizer securities during the Class Period. D

## COUNT II

**For Violation of §20(a) of the 1934 Act  
Against Pfizer, Kindler, McKinnell, D'Amelio, Levin, Shedlarz,  
Read, Feczko and Waxman**

158. Plaintiffs incorporate ¶¶1-157 by reference as if fully set forth herein. D\*

159. Defendants Kindler, McKinnell, D'Amelio, Levin, **Shedlarz**, Read, **Feczko** and Waxman acted as controlling persons of Pfizer within the meaning of §20 of the 1934 Act. By virtue of their positions and their power to control public statements about Pfizer described in detail in ¶¶24-31, 33, 35, defendants Kindler, McKinnell, D'Amelio, Levin, **Shedlarz**, Read, **Feczko** and Waxman had the power and ability to control (and did influence and control, directly or indirectly) the actions of Pfizer and its employees, including the content of Pfizer's financial statements, releases and conference call statements. Pfizer controlled the content of its financial statements, releases and conference call statements, its subsidiaries, the Individual Defendants and its other officers and employees. Pfizer had the power to hire, fire, supervise and otherwise control the actions of its employees.

#### PRAYER FOR RELIEF

WHEREFORE, plaintiffs pray for relief and judgment as follows:

- A. Declaring this action to be a proper class action pursuant to Fed. R. Civ. P. 23;
- B. Awarding plaintiffs and the members of the Class damages and interest;
- C. Awarding plaintiffs' reasonable costs, including attorneys' fees; and
- D. Awarding such equitable/injunctive or other relief as the Court may deem just and proper.

#### JURY DEMAND

Plaintiffs demand a trial by jury on all issues.

DATED: April 15, 2011

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